DECISION PARTNER INVOLVEMENT IN CANCER CLINICAL TRIAL PARTICIPATION

by
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ABSTRACT

Clinical trials help to advance scientific knowledge and provide novel therapies to patients, yet only 3-5% of adults with cancer participate in clinical trials. Gaps remain in our understanding about the role of decision partners in clinical trial decision making, which may be critical to clinical trial recruitment and retention. Decision partners are family and friends who are engaged in health care decision making. The purpose of this exploratory, descriptive dissertation was to examine relationships between individual patient factors, decision control preferences for decision partner involvement, and clinical trial participation (CTP). This mixed methods study included quantitative analysis of ongoing data from a parent study and a qualitative study. The two study aims were to: describe the relationships between patient factors, decision control preferences for decision partner involvement, clinical trial knowledge, attitudes, and beliefs (CTKAB), and CTP; and explore the process of decision making about CTP among persons with varying decision control preferences. Quantitative results (n=82) showed that there are some associations between CTP, CTKAB, and patient factors, though none of our findings were found to be statistically significant at p-value ≤ 0.05. This may possibly be due to the small number of participants who were actually offered a clinical trial (25%, n=21), leaving most participants unable to make a clinical trial decision. The qualitative study with patients and decision partners (n=24) provided insight into clinical trial decision-making among those with varying decision control preferences. Four themes emerged: Having the freedom to choose, Getting the most insight about clinical trials, Building relationships...trusting *someone* in the process, and Realizing readiness and context. In conclusion, providers still have an important influence in clinical trial decision making, but decision partners are often engaged at varying levels. Further research is needed to identify variations in decision control preferences across

diverse populations and over time, address barriers to clinical trial eligibility, examine relationships between providers and decision partners, and incorporate stated-preference methods.

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CHAPTER I: Introduction and Background

Introduction

Cancer is a major health concern and the second leading cause of death in the United States, second to heart disease (Salman, Nguyen, Lee, & Cooksey-James, 2016). Shortly after a cancer diagnosis, patients must make difficult treatment decisions, which may include a decision about participating in cancer clinical trials, given that some patients may and may not be eligible or offered clinical trials until later in their treatment trajectory. Clinical trials are research studies that helps pave the way for new treatments, protocols, and interventions to see if these new therapies are safe and effective in people. Clinical trials offer patients the opportunity to be treated using an investigational drug rather than standard treatment or enrolling in a different treatment protocol that may include a combination of different therapies. Participation in clinical trials is essential in cancer care to improve the overall care and well-being of this patient population, yet less than 5% of adults with cancer choose this option. Low accrual into clinical trials compromises the success of clinical trials, wastes valuable resources, and squanders an opportunity for improving patient outcomes (Bell & Balneaves, 2015).

Notably, any investigational drug has risks and benefits, including whether it is effective in treating the individual's cancer or causes harm. It is important to understand the barriers to participating in clinical trials experienced by cancer patients, as well as the personal, social, structural, and political contexts that impinge on patients' abilities to take part in clinical research (Bell & Balneaves, 2015). Although patients have individual autonomy in clinical trial decision making, given the complexity and risks involved, some patients may prefer to share decision control with decision partners. Decision partners are defined as family and friends who serve as trusted sources of information who may facilitate decision satisfaction or contribute to

decision regret in clinical trial decision-making (Wenzel, Mbah, Xu, Moscou-Jackson, Saleem, Sakyi, & Ford, 2015).

Background and Rationale

Significant gaps remain in our understanding of how patients decide to participate in research and who or what might be important in the decisional process. Patients often want to involve decision partners to navigate complex decisions. Understanding cancer patients' preferences for decisional roles is important in providing quality cancer care and ensuring patient satisfaction (Yennurajalingam, Parsons, Duarte, Palma, Bunge, Palmer, Delgado-Guay, Allo, & Bruera, 2013). Understanding these relationships is critical if we want to improve the clinical trial recruitment and retention, and it is important for clinicians and researchers to pay attention to the different relationship dynamics that patients have when promoting shared decision making (Symes et al., 2015).

Review of the Literature

Search Strategy. With the aid of a librarian, a comprehensive search was undertaken in EMBASE, CINAHL, and PubMed databases to identify English-language studies published between 2006 and 2017, with notable articles published as early as 1989. These original research articles addressed cancer patient populations, family research, motivating factors and barriers to clinical trial participation, and family involvement in treatment decision-making. The database search included the following keywords and MeSH terms: "decision making, family", "decision making", "decision-making", "decision making, patient", "collaborative OR shared", "decision making", "patient participation", "family", "clinical trials", "clinical trial", "neoplasms" "oncology", "cancer", tumor", "tumour".

Review of the Literature of Cancer Clinical Trial Participation. Clinical trials have produced prevention, treatment, and outcome advances, and nowhere has this been more evident than in cancer (Wang, Tsai, Chen, & Tsay, 2011; Barakat, Schwartz, Reilly, Deatrick, & Balis, 2014). Cancer clinical trials are necessary for the improvement of patient care as they have the ability to demonstrate the efficacy and safety of novel cancer treatments (Bell & Balneaves, 2015). Despite its role in advances, clinical trial participation among adults with cancer remains as low as 3-5%, with minority groups greatly underrepresented (Wang, Tsai, Chen, & Tsay, 2011; Brown, Cadet, Houlihan, Thomson, Pratt, Sullivan, & Siminoff, 2013; Buss, DuBenske, Dinauer, Gustafson, McTavish, & Cleary, 2008). Low participation rates have critically delayed scientific progress to derive treatments to fight cancer and reduce cancer health disparities (Brown et al., 2013; Albrecht, Eggly, Gleason, Harper, Foster, Peterson, Orom, Penner, & Ruckdeschel, 2008). In a recent analysis of trial accrual performance among adult oncology studies in the US, Cheng et al. reported 81.5% of trials did not achieve accrual goals within the anticipated accrual period (Bell & Balneaves, 2015; Cheng, Dietrich, & Dilts, 2011). Though we understand some barriers to clinical trial participation (Unger, Cook, Tai, & Bleyer, 2016; Lee, Ow, Lie, & Dent, 2016), there is a clear urgency to understand the decision-making process that influence enrollment.

Cancer research has become a national priority and requires the need for patients to participate in clinical trials (Altshuler, 2016). Yet, there are unknown benefits and risks associated with participation. Patients cannot predict whether the new treatments and interventions in clinical trials will improve or worsen their health outcomes. Additionally, clinical trials are often introduced early in treatment, when emotionality is intense, relationships with clinicians are new, and information overload is occurring (Thorne, Oliffe, Stajduhar, Oglov,

Kim-Sing, & Hislop, 2013). Hence, making decisions about clinical trial participation can often occur when patients are particularly vulnerable (Thorne et al., 2013; Rutten, Arora, Bakos, Aziz, & Rowland, 2005), taking additional physical and mental energy (Butow, Maclean, Dunn, Tattersall, & Boyer, 1997).

Review of the Literature of Role of Family and Friends. Decision-making about clinical trial participation is not often clear and straightforward. There are potential risks and benefits to consider beforehand. Many patients may depend on decision partners to get through the process. Extensive research has shown that a patient's family and friends play an integral role in patient decision choices about treatment (Hubbard, Kidd, & Donaghy, 2008; Lin, Pang, & Chen, 2013; Quinn, McIntyre, Gonzalez, Antonia, Antolino, & Wells, 2013; Laidsaar-Powell, Butow, Bu, Charles, Gafni, Fisher, & Juraskova, 2016; Shin, Cho, Roter, Kim, Sohn, Yoon, Kim, Cho, & Park, 2013). Whether or not family members are present, clinicians must conceptualize cancer care as a family issue because family members are often consulted by patients before medical visits and discuss their care and treatment options (Sharma, Hughes, Nolan, Tudor, Kub, Terry, & Sulmasy, 2011; Laidsaar-Powell et al., 2016). Family members and friends are not only the providers of social support, but also are the key participants in treatment decision-making (Shin et al., 2013; Lingler, Sherwood, Crighton, Song, & Happ, 2008).

Furthermore, research evidence suggests that the majority of patients prefer shared decision-making (Wei et al., 2016), and Quantitative studies show that a majority of cancer patients (49–84%) and family members (54–59%) prefer family participation in decision-making to some extent (Laidsaar-Powell et al., 2016; Pardon et al., 2010; Shin et al., 2013). In some cultures where decision-making involves the community and family, influencing attitudes and

opinions in the larger community may be an important first step before patient recruitment (Lee, Ow, Lie, & Dent, 2016). From an ethical standpoint, respect for autonomy requires physicians to take into a patient's preferences regarding medical decision-making, including the preference to involve the family (Pardon et al., 2010), and that the preferences in which patients have for involving families and friends should be viewed within the context of personal values and culture, such as familial obligation and loyalty (Clayman, Roter, Wissow, & Bandeen-Roche, 2005).

Review of the Literature of Other Influential Factors. There are multiple factors that may impact participation in clinical trials, including attitudinal, structural, and clinical barriers, physician and patient attitudes, and sociocultural factors (Unger, Cook, Tai, & Bleyer, 2016; Lee, Ow, Lie, & Dent, 2016). Patients' attitudes toward living with cancer affect whether they can decide to accept or decline participation (Kohara & Inoue, 2010). A conservative attitude towards risk-taking can be a barrier for patients and prevent them from participating in a clinical trial (Lee, Ow, Lie, & Dent, 2016). Patients may be unwilling to join a clinical trial if they perceive a worse risk-benefit ratio to joining as there may be unanticipated side effects combined with a perceived lack of efficacy data on the investigational drug (Lee, Ow, Lie, & Dent, 2016). Clinical and physician barriers may include clinical trial ineligibility, physicians may have a strong inclination toward a specific treatment for a given patient, physicians may also anticipate that the introduction of uncertainty about a clinical trial outcome will subvert patient confidence in their expertise, and fear that clinical trials will be too time-consuming (Unger, Cook, Tai, & Bleyer, 2016). Some facilitators to enrollment include late stage disease, sense of altruism (Truong, Weeks, Cook, & Joffe, 2011), trust in physicians, and prior positive experience with clinical trials (Lee, Ow, Lie, & Dent, 2016).

Gaps in the Literature. Patients' preferences for involving decision partners in decision-making may also be affected by the nature of the illness and the patient's relationship with the clinician and decision partner. Although it is known that families and friends are often engaged in cancer care and treatment, there is a knowledge gap in understanding the way in which those relationships, specifically with decision partners, influence the patient's own decision-making about clinical trial participation. The degree to which family members influenced patients' choices for the patients' own good (versus the family's good), how they were involved in the decision-making process, and patients' preferences with regard to the involvement of their family in clinical trial decisions remain largely unexplored (Bell & Balneaves, 2015). Research informed by the theoretical lens of relational autonomy is required to explore how cancer patients reach the decision to engage in a clinical trial both as an individual and as a social being embedded in relationships (Bell & Balneaves, 2015). Hence, there is a need to examine the relationships between individual patient factors, decision control preferences for decision partner involvement, and clinical trial participation.

Purpose of Dissertation Research

The purpose of the dissertation is to examine the relationships between individual patient factors, decisional control preferences for decision partner involvement, and clinical trial participation.

Specific Aims/Hypotheses

The specific aims and hypotheses of this dissertation were:

AIM 1: To describe the relationships between Patient Factors (Decision Control Preferences, Age, Gender, Education, Marital Status, Race, Ethnicity), Clinical Trial Knowledge, Attitudes, and Beliefs, and Clinical Trial Participation.

Hypothesis 1.1: Individual patient factors are associated with clinical trial participation. *Lower educational attainment will be associated with decreased participation in a clinical trial. Younger age will be positively associated with clinical trial participation.*

Hypothesis 1.2: Knowledge, attitudes and beliefs will be associated with clinical trial participation. *An increased clinical trial knowledge level and more positive attitudes and beliefs about clinical trials will be positively associated with a patient's decision to participate in a clinical trial.*

Hypothesis 1.3: Educational attainment will be associated with decision control preference. *Higher education attainment will be associated with a higher level of decisional control preference.*

Hypothesis 1.4 Decision control preferences will be associated with clinical trial participation. *Preferences for a more deferred decision style will be positively associated with patient's decision to participate in a clinical trial.*

AIM 2: To explore the process of decision making about clinical trial participation among persons with high levels of decisional control preferences and those with a more deferred decision style.

Significance of Research

When making decisions about clinical trials, it is crucial to understand patients' decision control preferences for involving decision partners in decisions about clinical trial participation. In an era of increasing emphasis on shared treatment decision-making and on the principle of relationality, the opportunity for patients to identify how they prefer the involvement of decision partners in the process is critical to treatment decision satisfaction and clinical trial retention

(Unger, Cook, Tai, & Bleyer, 2016), especially when research has shown that cancer decisions are not so simple (Reyna, Nelson, Han, & Pignone, 2015). A patient's decision about which cancer treatment to receive is complex and deeply personal (Unger, Cook, Tai, & Bleyer, 2016). Patients may want to expand the concept of shared decision making from patient-provider to also involve decision partners. The role of decision partners is worth examining because their involvement could potentially aid or impede decision-making about clinical trial participation. Our research findings have the potential to guide interventions that may improve clinical trial recruitment and retention for the advancement of cancer care.

Dissertation Organization

This dissertation is organized into 5 chapters. This first chapter introduces the need for the study by providing background, rationale and significance of the research followed by the specific aims. The second chapter describes the methodology of the dissertation study, including detail about the parent study schema. The third chapter (manuscript one) reviews the concept of decision partner and synthesize evidence from published studies that employ it in an effort to better understand its definition, attributes, and usefulness in the areas of patient and family health care decision making. The fourth chapter is an examination of the relationship between Patient Factors (Decision Control Preferences, Age, Gender, Education, Marital Status, Race, Ethnicity), Clinical Trial Knowledge, Attitudes, and Beliefs, and Clinical Trial Participation. The fifth chapter describes the qualitative findings that explored the process of decision making about clinical trial participation among persons with high levels of decisional control preferences and those with a more deferred decision style. The sixth chapter summarizes the findings of the previous chapters in the context of other family research and describes the potential areas of research for future work.

CHAPTER II: Dissertation Methodology

This dissertation contains a mixed-methods design comprising of a quantitative arm and a qualitative arm. This chapter describes detail about the methodology used in the dissertation study.

Conceptual Framework

This dissertation study addresses a knowledge gap by providing insight into the potential ways that patients involve decision partners when making difficult decisions about cancer clinical trial participation. The study was guided by a Conceptual Model of Decision Partner Engagement in Cancer Clinical Trial Decision-Making, developed from the following two models: (1) The Decision Making Ecology (DME) Framework and (2) the Model of Cancer Clinical Trial Decision-Making. The DME Framework (Figure 1) was originally developed to guide the decision-making for child protective services workers when they make decisions about an individual child case (Maguire-Jack & Font, 2014). It provides a theoretical and testable basis for understanding the context, process, and outcomes or consequences of child welfare decision-making (Fluke, Baumann, Dalgleish, & Kern, 2014). This framework was intended to provide an understanding of both the context and process of decision-making and to predict "behavioral thresholds for action" (Fluke, Baumann, Dalgleish, & Kern, 2014). Multiple influences for decisions are addressed within the framework, including individual patient factors and external forces (Baumann, Dalgleish, Fluke, & Kern, 2011). Components of this framework provides an overall understanding of the individual and social factors that contribute to patient decision choices, including micro- and macro- perspectives (Maguire-Jack & Font, 2014; Kozlowski & Klein, 2000).

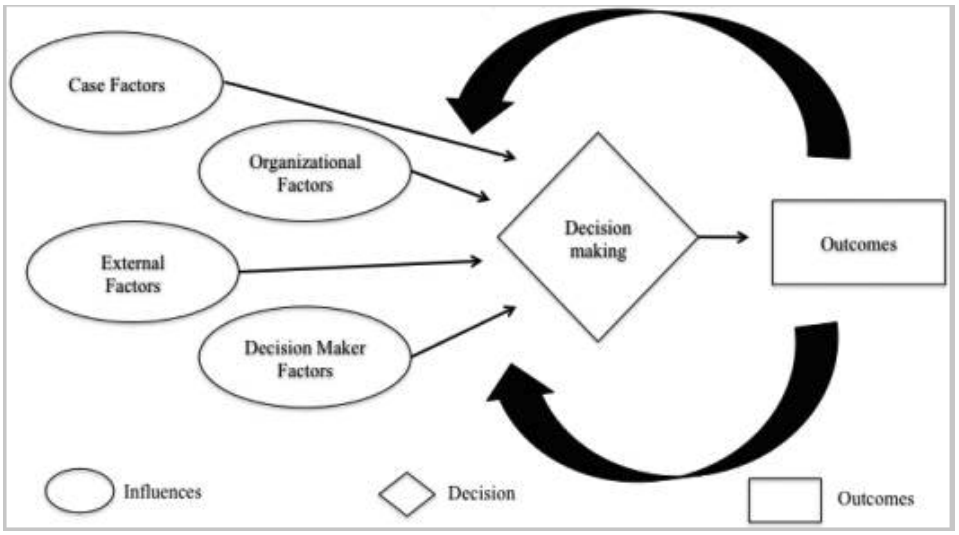

Figure 1. Decision Making Ecology Framework. (Baumann et al., 2011)

The Model of Cancer Clinical Trial Decision-Making (Figure 2), which includes both inter- and intra-personal influences surrounding clinical trial decision-making (Wenzel, Mbah, Xu, Moscou-Jackson, Saleem, Sakyi, & Ford, 2015), has also been incorporated in the overall study framework. It was originally developed from data collected among clinical trial-eligible African American cancer patients to better understand research decision-making (Wenzel et al., 2015). In this study, the researchers found that participants who chose to participate reported the importance of support from family and friends and/or spiritual motivation to participate (Wenzel et al., 2015). Though originally developed from focus groups with African American adult cancer patients, clinicians and researchers have commented on the broader applicability of many components, especially the inclusion of decision partners. Thus, the model helped to guide the

dissertation study, which included a racially/ethnically heterogeneous sample.

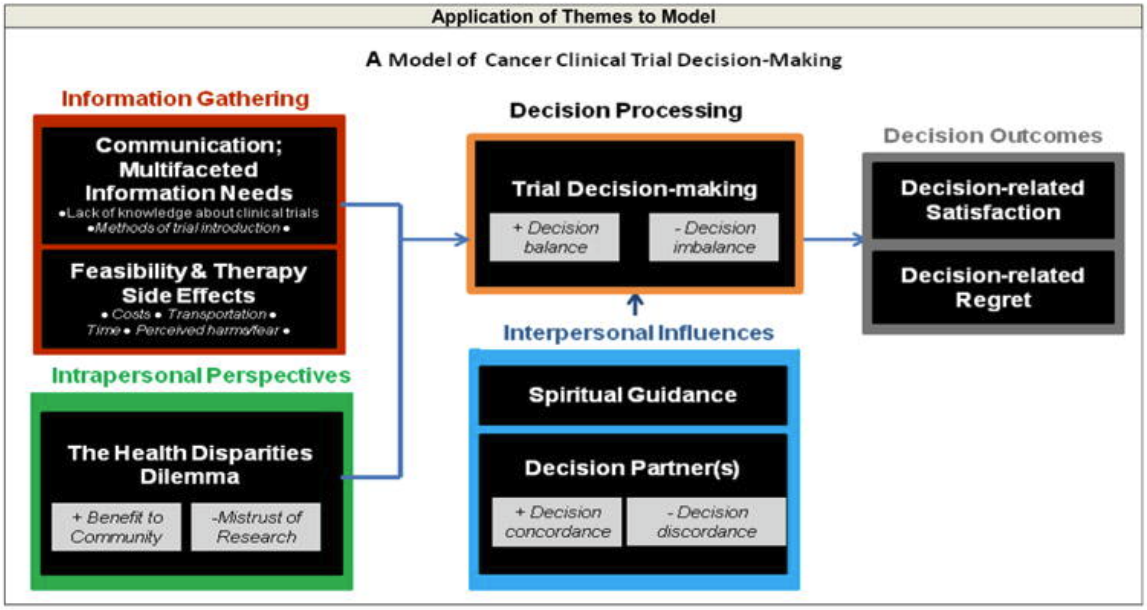

Figure 2. The Model of Cancer Clinical Trial Decision-Making (Wenzel et al., 2015)

For the dissertation study, the outcome variable was clinical trial participation (yes, no, not offered/delayed offer); the independent variables and covariates were individual patient factors (age, race, ethnicity, gender, education level, clinical trial knowledge, attitudes, and beliefs, decision control preferences for decision partner involvement), and interpersonal decision partner factors. The Conceptual Model of Decision Partner Engagement in Cancer Clinical Trial Decision-Making, the theoretical framework for the dissertation, is depicted Figure 3. The systemic context for decision-making includes a set of decision-making influences displayed as ovals, including case-specific factors, external or decision partner factors, and individual factors that combine in various ways to influence decisions and outcomes (Fluke, Baumann, Dalgleish, & Kern, 2014).

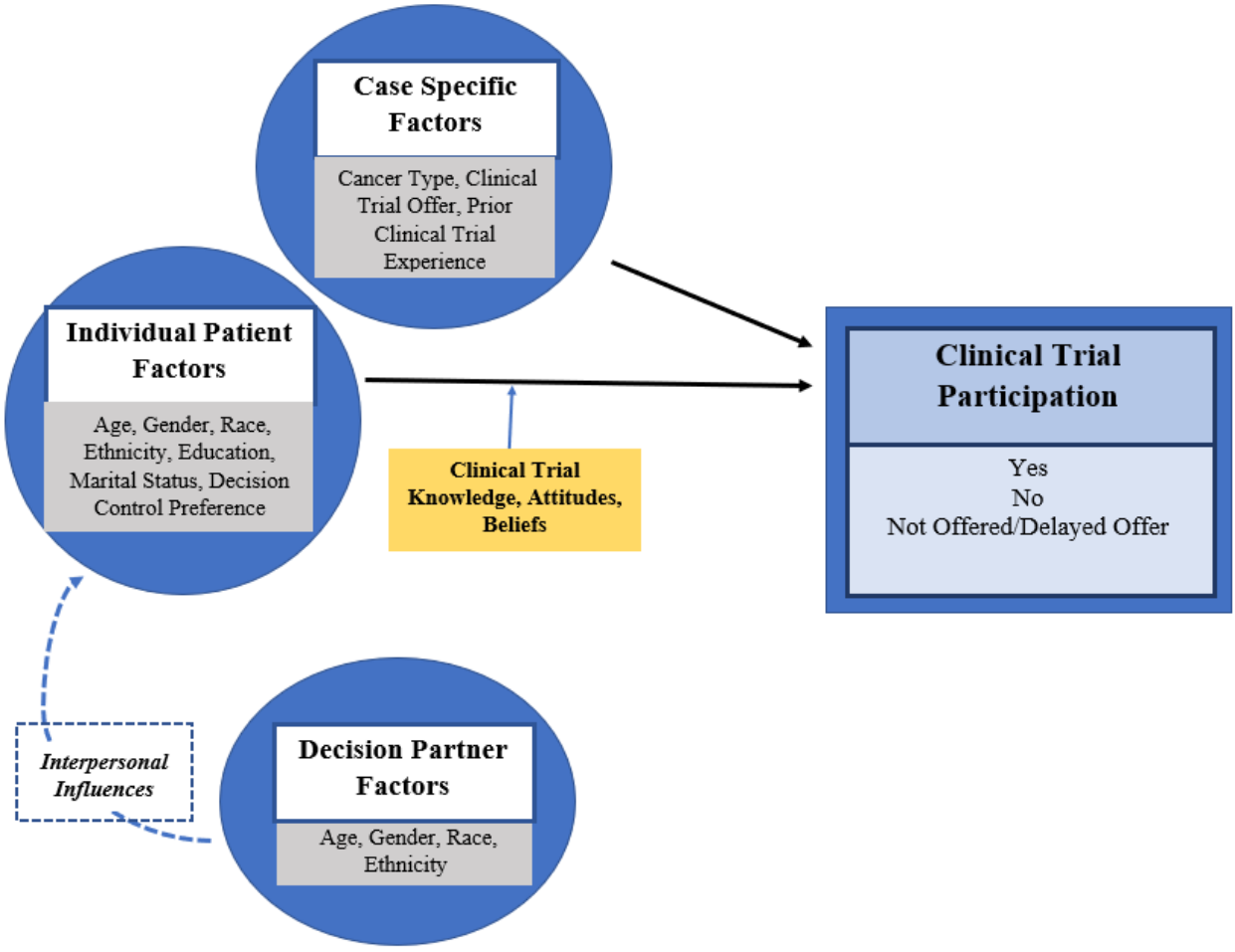

Figure 3. The Conceptual Model of Decision Partner Engagement in Cancer Clinical Trial Decision-Making

Parent Study Design. The dissertation study was a nested study within the parent study entitled EMPaCT Patient Navigation Study. The objective of this parent study was to increase recruitment and retention of racial/ethnic minorities into therapeutic clinical trials through the well-established EMPaCT consortium with the ultimate goal of reducing cancer-related health disparities. Specifically, the consortium is a national system that used a coordinated approach with five consortium institutions to address accrual into clinical trials on multiple levels. The EMPaCT Patient Navigation Study was a randomized trial conducted with the purpose of

implementing and evaluating a patient navigation program designed to increase recruitment and retention of minority patients into therapeutic cancer clinical trials. In this study, community patient navigators work with oncology nurses and other clinicians to help patients overcome barriers to participation and navigate through the healthcare system. For the parent study, participants were randomized to High Intensity Clinical Trial Navigation (Intervention Arm) or to Low Intensity Navigation (Control Arm). The target recruitment sample for the parent study was 110 participants. This parent study had ongoing data collection while the dissertation study was being conducted.

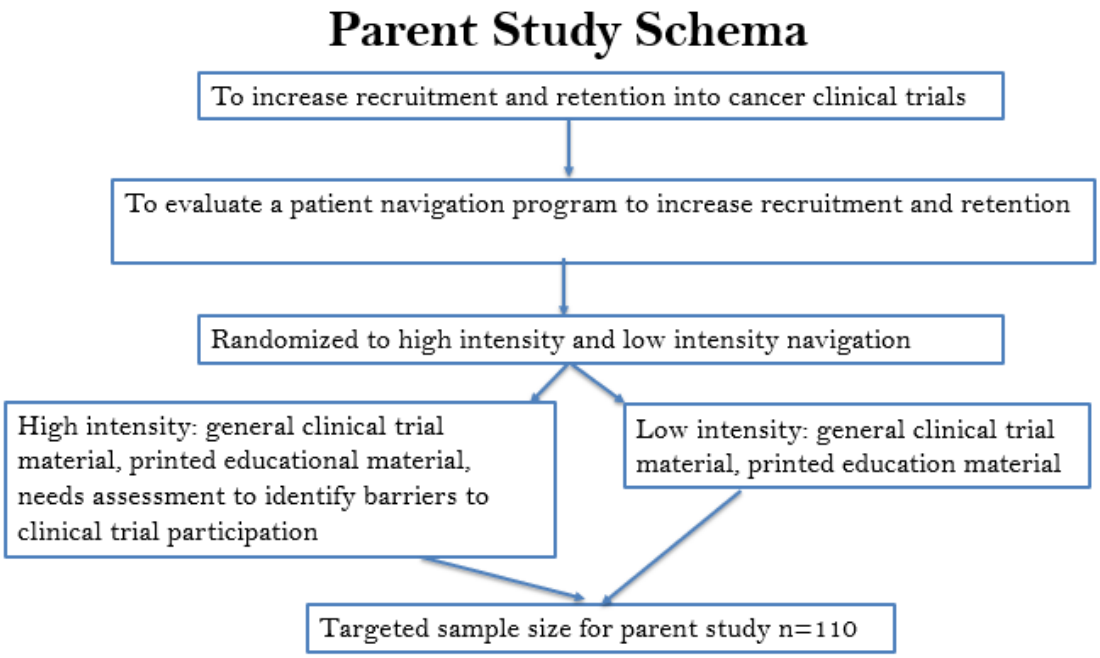

Figure 4. Parent Study Schema

Dissertation Study Design. Study variables were selected from the parent study based on relevance to the dissertation study purpose, and address factors relevant to the conceptual model. Inclusion and exclusion criteria for this dissertation study were the same as for the parent study. The sample size for this dissertation study was 82 individuals. The dissertation study had a cross-sectional explanatory sequential mixed methods study design using existing quantitative data

from the parent study. Thus, this study is composed of an analysis of ongoing quantitative patient data, including the addition of decision control preference data using a modified version of the Control Preferences Scale, decision partner factors, and primary qualitative data collection. Data points that were also collected for decision partners included age, gender, race, and ethnicity. The occupation and work experiences of decision partners also emerged as data from the interviews. The qualitative interviews followed quantitative data collection. Qualitative participants were purposively sampled from respondents of the quantitative arm to participate in interviews based on a maximum variation of scored preferences for decision partner involvement on the modified Control Preference Scale. This phase involved a smaller number of patient participants (n=12) who all had an available clinical trial based on a screening algorithm and decision partner participants (n=12). Details of the study schema is found in Figure 5.

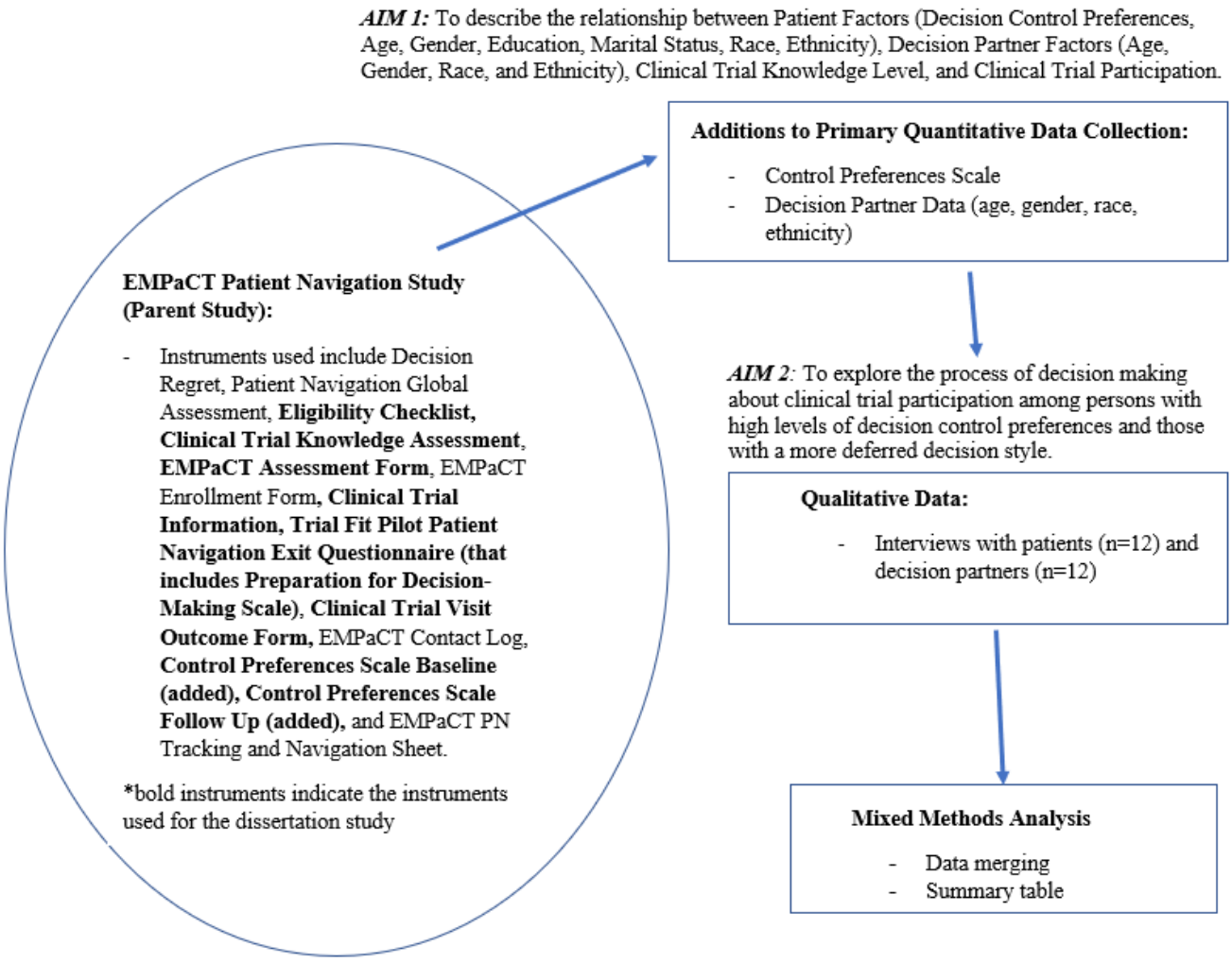

Figure 5. Dissertation Study Schema

Quantitative Study Methods

Study Aim

AIM 1: To describe the relationships between Patient Factors (Decision Control Preferences, Age, Gender, Education, Marital Status, Race, Ethnicity), Clinical Trial Knowledge, Attitudes, and Beliefs, and Clinical Trial Participation.

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Hypothesis 1.4 Decision control preferences will be associated with clinical trial participation. *Preferences for a more deferred decision style will be positively associated with patient's decision to participate in a clinical trial.*

Research Variables.

A list of the major variables and instruments used in the analyses are described below:

Sociodemographic Factors

Patients reported their age, gender, highest level of educational attainment, marital status, race, and ethnicity as key sociodemographic factors obtained for the study. Sociodemographic factors are those modifiable and unmodifiable patient and decision partner characteristics that may influence the decision regarding cancer clinical trial decision-making. Sociodemographic

factors are socially constructed and have been shown to be predictors or characteristics of cancer patients who participate in clinical trials. The categories for gender included male and female. The categories for race were: African American or Black, White, Asian or Asian American, American Indian or Alaska Native, and Native Hawaiian or Pacific Islander, or Other. The categories for ethnicity used in this study were Hispanic or Latino and non-Hispanic or Latino. The options for educational attainment included 8th grade or less, 9th-11th grade, high school graduate, some college, community college/technical, bachelor's degree, master's degree, doctoral degree, and missing/unreported. The options for marital status included single, married, separated or divorced, widowed, lives with partner, and missing/unreported. Information was obtained through electronic medical records and patient self-report.

Cancer Type

The cancer type is defined as the primary tumor site of the patient. Generated from our study sample, data regarding the specific cancer type was used in analysis. There was a wide array of solid tumor cancer diagnoses represented by our study sample, including breast, prostate, multiple myeloma, ovarian, head and neck, and endometrial.

Clinical trial knowledge, attitudes, and beliefs assessment (CTKAB)

Study participants were asked about their knowledge, attitudes, and beliefs about clinical trials using the 18-item Clinical Trial Knowledge, Attitudes, and Beliefs Assessment. Participants responded to statements such as "The information gained from clinical trials may help a friend or family member", "I think all patients who are eligible should be asked to take part in clinical trials", "I would only take part in a clinical trial if I thought that my own health would benefit". The entire assessment can be in found in Appendix E. The survey has been shown to have a Cronbach alpha of 0.661. Responses were originally developed, by principal

investigators of the parent study, for patients to report on a five-point Likert scale that ranged from 1(strongly agree) to 5 (strongly disagree). The assessment was reverse coded to have higher scores reflect having more knowledge and more positive attitudes and beliefs about clinical trials. After the reverse scoring, an additive scale score could range from 18 to 90; high scores indicate higher knowledge and more positive attitudes and beliefs about clinical trials. We decided to include this questionnaire in our study because research indicates that cancer patients who are offered or enrolled may have low levels of knowledge about clinical trials (Cox, 2000) or misperceptions about how they function (Curbow, Fogarty, McDonnell, Chill, & Scott, 2004; Itoh et al., 1997). In general, research has shown knowledge deficits (Curbow, Fogarty, McDonnell, Chill, & Scott, 2004; Ellis & Butow, 1998). Cox (2000) conducted a series of four interviews with 55 patients with advanced cancer who were offered participation in Phase I or Phase II trials. Results indicated that only 16% of the patients could explain the purpose of the clinical trial they were offered. Patients have been shown to decline participation if the information about the clinical trial was difficult to understand (Curbow, Fogarty, McDonnell, Chill, & Scott, 2004; Lovegrove, Rumsey, Harcourt, & Cawthorn, 2000). Moreover, with increasing numbers of studies on research ethics and a need to improve the recruitment of research subjects, the ability to measure attitudes toward biomedical research has become important (Rubright, Cary, Karlawish, & Kim, 2011).

Decision Control Preferences

Decisional control is often used in the decision science literature to describe patients' ability to play an active role in making decisions about their treatment (Ghane, Huynh, Andrews, Legg, Tabuenca, & Sweeny, 2014). It refers to patients' specific role in a treatment decision process rather than a broad approach to health care (Edwards & Elwyn, 2006). We measured

participants' decision control preferences for decision partner involvement using the Control Preferences Scale (CPS). The original scale has been used and validated in several studies to assess the degree of control patients prefer over medical decisions with their doctors (Degner & Sloan, 1992). The question and five response options of the original scale include, "How do you prefer to make medical decisions with your doctors?: 1) I make all medical decisions on my own; 2) I make the final decision myself only after considering my doctor's opinion; 3) My doctors and I share decision making equally; 4) My doctors make the final decision for me only after considering my opinion; 5) My doctors make all medical decisions for me." (Degner & Sloan, 1992; Chiu, Feuz, McMahan, Miao, & Sudore, 2016).

For our study, we modified the scale to assess decision control preferences that patients had for involving decision partners in treatment decisions, rather than measuring their decision control preferences with providers. On this scale, for Part A, patients could pick one statement out of five that best describes their preferred involvement in treatment decision making. The decision control preferences could range from patients reporting: (1) I prefer to make the final decision about which treatment I will receive; (2) I prefer to make the final decision about my treatment after seriously considering the opinion of my family/friends; (3) I prefer that my family/friends and I share responsibility for deciding which treatment is best for me; (4) I prefer that my family/friends make the final decision about which treatment I will receive, but seriously consider my opinion; or (5) I prefer to leave all decisions regarding my treatment to my family/friends. There is also a subcomponent of the Control Preferences Scale, Part B, that evaluates patients' preferences regarding whether their (1) doctor's input weighs most heavily in decision-making; (2) My family/friends' input weighs most heavily; or (3) My doctor's input and my family/friends' input are equally important. To maintain a sufficient number of cases for

statistical analysis per category, we grouped answer options in Part A into two categories that included high decision control preference and deferred decision style. Response 1 was coded to represent high decision control preference (high DCP). Responses 2, 3, 4, and 5 were grouped to reflect a deferred decision style. Table 1 describes the two recoded categories.

Cancer clinical trial participation.

The primary outcome measure for the study was clinical trial participation among the adult cancer patient-participants. Clinical trial participation was determined through medical record review and self-report. There were three different responses for this variable, including (1) yes, (2) no, (3) not offered/delayed offer.

Setting.

Study participants were recruited from the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center (SKCCC) outpatient clinic. The SKCCC was one of the first cancer centers in the country designated by the National Cancer Institute (NCI) as a Comprehensive Cancer Center. The SKCCC provides care for pediatric and adult patients and encompasses a wide spectrum of specialty programs in breast, lung, prostate, pancreatic, colon and rectal, melanoma, ovarian, multiple myeloma, hematologic malignancies, and head and neck cancers. It is one of two NCI-designated Comprehensive Cancer Centers in the state of Maryland.

Recruitment and Sampling.

The targeted sample for the quantitative arm of the dissertation study included adult cancer patients who had an available therapeutic clinical trial, identified through a medical record review and a specific content expert-derived screening algorithm created by research nurses and oncologists at the SKCCC. Patients who were screened as having an available

therapeutic clinical trial through available algorithms were contacted by phone prior to their scheduled oncology visit. The goal of this pre-visit call was to introduce and determine patient interest in participating in the parent study. Participants for the dissertation study were first screening using the eligibility criteria of the parent study. Inclusion criteria included: over the age of 18, had a primary solid tumor cancer diagnosis (breast, ovarian, colon, lung, pancreas, prostate, multiple myeloma, or head and neck), had an identified available therapeutic clinical trial, and a Maryland resident. All participants were either newly diagnosed or new referral patients in the Johns Hopkins Health System. Exclusion criteria included those persons who were not Maryland residents, did not speak or understand English, and who did not have an identified available clinical trial identified through EPIC screening.

Data Collection.

Quantitative data collection occurred over a 24-month period from March 2016 to March 2018 in the SKCCC outpatient clinic. On the day of the oncology visit, informed consent was obtained for the parent study and baseline data were collected. In line with the parent study protocol, participants received no financial compensation in completing the quantitative arm of this study.

Ethical Procedures.

Ethical approval for this study was obtained from the Johns Hopkins Medicine Institutional Review Board (JHM IRB) (NA_00072282). The study design and questionnaires were all approved by the JHM IRB. Participants were told that (a) their participation was entirely voluntary, (b) their confidentiality would be protected by de-identifying data and assigning study ID numbers, (c) their participation would not affect their care at SKCCC, and (d) they could contact the researchers or the IRB with any questions or concerns. The Clinical Research

Management System (CRMS) is a web-based tool designed to organize and streamline clinical research management and was used in the study for data and safety monitoring. CRMS is maintained in a secure location and accessible to all study team members with a valid Johns Hopkins ID. Using a computer-based data entry system, the identifications was entered into REDCap, a password protected, HIPAA-compliant, using a Johns Hopkins-based secure study server. All hard copies of study data were locked and stored in secure data files at the School of Nursing and at a Johns Hopkins Medicine-affiliated building, accessible only to this researcher and members of the study team. All screening and completed survey forms that contained participant information were scanned into JH Box, a secure university server designed for document sharing with other study team members.

Data Analysis Plan.

Descriptive and Exploratory Statistics. First, exploratory data analysis was conducted to check for assumptions, outliers, missing data, and data consistency. Graphical methods, including histograms, were generated to examine the data. Descriptive statistics were compared and used to summarize the sample and instrument characteristics. Baseline demographic data and measurement scores were used for the analysis of the aims and hypotheses. Continuous variables were summarized using mean and standard deviation (SD) and medians with interquartile ranges (IQR). Categorical variables were summarized using frequencies and percentages. Sample demographics of the sample were calculated, including mean age and standard deviation, percentages by gender, frequencies by educational level, marital status, clinical trial offer, cancer type, decision control preference, race/ethnicity, and mean clinical trial knowledge, attitudes, and beliefs score.

A series of scatter plots were conducted and analyzed to determine the appropriate covariates to include in the regression models. Bivariate analyses using Chi-square tests (e.g. correlation between two continuous variables, use of a scatterplot, or cross-tabulation with two categorical variables) and Fisher's exact test to examine the associations between variables and the p values were also obtained. A p-value of ≤ 0.05 was considered statistically significant. T-tests were used to examine differences in clinical trial knowledge, attitudes, and beliefs scores by gender. We also performed a one-way ANOVA to determine whether there were any statistically significant differences between the mean ages of the three groups of clinical trial participation (yes, no, not offered/delayed offer). Due to the smaller percentage of patients who were actually offered a clinical trial, we were not able to perform logistic regression to examine predictors of the clinical trial participation. We were able to conduct exploratory analyses, including linear regression, to examine predictors of clinical trial knowledge, attitudes, and beliefs. Statistical analyses were performed with SPSS statistical software.

Qualitative Study Methods

Study Design. An exploratory descriptive design was used to elicit first-hand descriptions of individual experiences and perspectives with decision-making related to clinical trial participation from the perspectives of adult cancer patients and their decision partners.

Study Aim:

AIM 2: To explore the process of decision making about clinical trial participation among persons with high levels of decisional control preferences and those with a more deferred decision style.

The goal of the qualitative study phase was to explore how adult cancer patients in the outpatient cancer setting, as well as their decision partners, approach clinical trial decision-making based on patients' decision control preferences.

Recruitment and Sampling.

Study participants were recruited from the outpatient oncology clinics at the Johns Hopkins Sidney Kimmel Comprehensive Cancer (SKCCC), which provides inpatient and outpatient care for pediatric and adult patients. Participants in this study phase included both patients and decision partners who the patients self-reported, although two patients chose not to identify a decision partner for the study. We selected patients who decided to participate and those who decided not to participate in a cancer clinical trial, as well as those who were not offered a clinical trial at the initial clinic visit when baseline data were being collected for the parent study in spite of all patients being screened to have an available clinical trial. Patients recruited for the qualitative study were already consented and enrolled into the parent study and completed the quantitative phase data collection. Additional inclusion criteria included that the patients had completed the Control Preference Scale. The inclusion criteria for decision partners included being 18 years or older, and who were able to read, write and understand English, and identified as a decision partner by the patient. Each participant in the qualitative study phase received up to $30 and a parking voucher as needed. Sample characteristics are summarized in Table 3 in Chapter V.

Methodology.

We interviewed patient/decision partner groups from a variety of reported scores on the modified version of the Control Preference Scale. Participants were selected for interviews based on whether the patients completed the CPS. We grouped answer options about decision control

preferences for decision partner involvement into two categories that included high decision control preference and deferred decision style. Response 1 was coded to represent high decision control preference (high DCP). Responses 2, 3, 4, and 5 were grouped to reflect a deferred decision style. Table 1 describes the two recoded categories.

Table 1. Grouped Categories for Patients' Decision Control Preferences

High DCP	Deferred DCP
"I prefer to make the final decision about which treatment I will receive"	"I prefer to make the final decision about my treatment after seriously considering the opinion of my family/friends" "I prefer that my family/friends and I share responsibility for deciding which treatment is best for me" "I prefer that my family/friends make the final decision about which treatment I will receive, but seriously consider my opinion" I prefer to leave all decisions regarding my treatment to my family/friends"

Data Collection. A semi-structured interview guide was developed by the study team through formative exploration of the available literature, clinical experiences and input, and informal discussions/review. The factors that influence clinical trial decisions, perceived role of decision partners in clinical trial decision-making, and perceptions about clinical trials were identified as gaps in the current literature that could be addressed in the qualitative study phase. Data collection occurred from November 2017 to March 2018. Interview dates, times, and locations were negotiated at the convenience of participants. Interviews were, on average approximately twenty-five minutes in length. Interviews took place either via telephone, video, or face-to-face. Participants had the option to choose to participate in individual interviews, dyadic interviews, or separate interviews with their decision partner present if the patient had

identified a decision partner in order to maximize participants' comfort level. Each audio-recorded interview was professionally transcribed verbatim; transcripts were cross-checked for accuracy and de-identified prior to analysis.

Ethical Procedures.

Ethical approval for this study was obtained from the Johns Hopkins Medicine Institutional Review Board (JHM IRB) (NA_00072282). The study design, oral questionnaire related to sociodemographic factors of decision partners, oral consent, and the interview guide questions were all approved by the JHM IRB. Prior to the start of each interview, oral consent was obtained for this additional study phase per the institution's IRB requirements. Participants were told that (a) their participation was entirely voluntary, (b) they could decline to answer any question that made them uncomfortable and could add any comments that were not elicited by the interview guide, (c) their confidentiality would be protected by de-identifying transcripts and demographic questionnaires and using pseudonyms in all reporting of results, and (d) they could contact the researchers or the IRB with any questions or concerns. No interview questions were unanswered because of participant refusal. Some questions, however, were irrelevant for some participants and no response was given. To provide privacy and confidentiality, all participants' names have been omitted, de-identified, and replaced with a numerical pseudonym and only those details we interpreted as necessary to understand the findings were reported.

Data Analysis.

The final sample size was determined by the number of interviews required to reach informational redundancy, and data saturation was determined after conferring with data coders and consulting qualitative research mentors. Transcriptions were checked for accuracy, and then uploaded the transcripts into Nvivo Version 11 to organize data and facilitate analysis. We

analyzed the data using the method of hermeneutic phenomenological analysis, which involves the reflection on the data, explication of themes, and discernment of patterns to fully understand the essence of the lived experience for participants, with a focus on their shared experience (Bynum & Varpio, 2018). Two coders completed line-by-line review of each interview and performed the first phase of analysis independently. Transcripts were first read several times independently by the two coders to allow for general impressions for the content to develop into categories and preliminary codes. Pre-coding, also known as first-level coding, was the first step of the analytical process that included circling, highlighting, underlining, or bolding, rich or significant quotes or passages that were particularly notable (Saldana, 2016). The data were then individually coded and analyzed by both coders who participated in weekly analysis meetings. We analyzed a subsample of the coded segments at the beginning of the coding process to verify the coding scheme and inter-rater agreement.

Next, the process of inductive analysis continued as categories emerged from coded segments, a process known as second-level coding (Saldana, 2016). We then compared second-level codes of data to conceptualize the codes into themes that describe the meaning of experiences related to the process of decision-making about clinical trial participation. Once a codebook was developed, all codes were reviewed and collapsed into categories and themes through an iterative process of classifying, comparing, grouping, refining and data reduction (Sandelowski, 2000; Bakitas, Dionne-Odom, Jackson, Frost, Bishop, & Li, 2016). Themes were defined as clusters of linked categories that convey similar meaning. The primary coder returned often to the audio recordings and transcripts through a recursive process to verify interpretations and applications of the codes and themes. Once preliminary findings were decided on between the two coders, findings were shared with the content and methods experts and peers. Any

coding discrepancies were also brought to the larger study team, and a final decision was made after further discussion that included a re-evaluation and comparison of the coded data. After receiving input from the research team, study findings were refined, as presented below.

We enhanced study trustworthiness, including credibility, dependability, and transferability (Graneheim & Lundman, 2004) via four strategies. First, we maintained an audit trail of study activities, including field notes from each interview. Methodological and analytical memos were also used for documenting decisions related to refining and defining codes, patterns, or categories as a way to document communications from the research team. This allowed the coders to recognize and separate his or her own thought processes from those of the participants. Second, the primary interviewer had expertise in both clinical practice and research of pediatric and adult cancer patients, and peer and expert reviewers had experienced with qualitative analyses focusing on chronic illnesses and family research. Third, at each stage, coding was completed by two researchers, and discrepancies were discussed and clarified. Fourth, dependability was obtained by having the same researcher conduct all interviews over a relatively short period of time (4 months). Overall, data analysis was an iterative process to support thematic analysis (Braun & Clark, 2006) that involved discussions of the analytic decisions with members of the research team until a consensus was reached.

CHAPTER III: Manuscript One: A Concept Analysis of Decision Partner

This concept analysis is the first of the three papers that comprises this dissertation. It is the author's intent to submit this paper to *Nursing Outlook*. The required format for submission is American Psychological Association (APA), Sixth Edition with references arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year is identified by the letters 'a', 'b', 'c', etc., placed after the year of publication. For this journal, there is no definitive word count for a concept analysis article nor a limited number of required references, and abstracts are limited to 150 words. The article structure includes clearly defined sections including an introduction, methods, findings, discussion and recommendations, conclusions, and appendices.

Title: DECISION PARTNER: A CONCEPT ANALYSIS AND IMPACT ON HEALTHCARE DECISION MAKING

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Abstract

Background: The decision partner concept has primarily been used in oncology. There is a need for greater precision and consensus surrounding its conceptual definition and use in broader populations.

Purpose: The purpose of this concept analysis was to define and describe the decision partner concept within the context of healthcare decision making.

Methods: The Walker and Avant method of concept analysis was applied to explain the antecedents, attributes, related concepts, and consequences of the concept, with major themes identified.

Discussion: A unifying definition and discussion of the decision partner concept is proposed. Our analysis offers promising direction in refining the concept across various diseases and medical encounters.

Conclusion: Findings have implications for reforming policy, practice, and research by drawing attention to developing conceptual frameworks and empirical research that refine its antecedents, attributes, consequences, and instruments to measure the concept to lead to interventions that facilitate decision partner inclusion in decision-making.

Word Count: 150

Keywords: decision making, dyad, partner, interpersonal, decision partner, decision control preference, relationality

Introduction

In medical encounters, patients make complex healthcare decisions and often involve and rely on family members in decision-making. Undoubtedly, decision-making occurs within the context of wider social networks and is not necessarily only a dyadic process between the patient and the health-care provider, which previous published literature in this area has tended to assume (Schumm, Skea, McKee, & N'Dow, 2010; Ballard-Reisch & Letner, 2003). Given the numerous decisions that patients make in short periods of time, families' impact on patients' decision making can be profound (Zhang & Siminoff, 2003). For the context of this article, family is defined as any individual who plays a significant role in another person's life and can be an intimate partner, spouse, close friend, or blood relative. Family members are relied upon for both emotional and practical support (Shin, Cho, Roter, Kim, Sohn, Yoon, Kim, Cho, Park, 2013), and the nature and degree of family involvement can be highly variable (Hobbs et al., 2015; Laidsaar-Powell et al., 2016[a]; Shin et al., 2013).

Although, patient autonomy, or the capacity to make decisions independently, is greatly recognized and valued in health care, there is a need to acknowledge that patients do not always make decisions in isolation. From an ethical standpoint, Beauchamp and Childress have maintained the principle of "respect for autonomous choices of persons", however, they then quickly add that they see autonomy as being neither a rejection of the "social nature of individuals" (DuBois, 2007; Qualtere-Burcher, 2009). The principle of autonomy posits that human beings are capable of making rational choices that determine their actions and themselves (DuBois, 2007). However, in order to be autonomous, a person must not only understand the information about a decision, but they must be able to use it (Herring, 2016). In this article, we recognized a need to acknowledge the principle of relationality, which denotes respect for human

beings insofar as they are essentially related to other human beings (DuBois, 2007). This principle recognizes that in order to flourish, actions must respect the relationships that an individual is in or should be in (DuBois, 2007). Ethicists argue that people develop their understanding of self and their goals in terms of relationships with others (Herring, 2016).

Therefore, understanding the structure and enactment of the decision-maker role in family interaction can provide insight into how individuals and/or family members perform the decision-making role within a cultural context that values autonomy and self-determination in combination with collective family actions in decision-making (Trees, Ohs, & Murray, 2017). Inarguably, family members can have an influential role in shared decision-making, with a goal of arriving at decisions that meet the patient's needs at that point in time (Clayman, Gulbrandsen, & Morris, 2017). Therefore, it is important to expand the concept of shared decision-making to not only capitalize on the patient-clinician relationship, but also to foster an interactive process whereby patient, family, and clinician can negotiate an agreed-upon decision (Montori, Gafni, & Charles, 2006; Bae, 2017; Alden et al., 2017). Specifically, more attention should be given to explicitly define and describe these decision partners, who are the family, close friends, and others engaged in healthcare decision-making with the patient by conducting a concept analysis.

Selection and Purpose of the Concept Analysis

The first step in a concept analysis is the selection of a concept. Concepts are important building blocks of knowledge, thought and communication, but to be truly useful they must be defined and clarified (Wahlin, 2017; Waltz, Strickland, & Lenz, 2010). For this concept analysis, decision partner was the concept that was chosen as the area of focus. Understanding this concept is critically important, particularly as patients with varying health conditions and medical encounters face different healthcare decisions and often rely on others for support.

Undiscerning to any singular health condition, the decision partner concept recognizes that many patients rely on and are influenced by close family and friends in healthcare decision-making. These individuals (family, friends) have been referred to and studied in many ways, but more efforts must be made to address their role and unique contribution in healthcare decision-making. Currently, there is a noticeable absence and lack of a clear definition of the decision partner concept as well as a diffuse understanding in the literature.

The second step in the concept analysis is to determine its purpose, which is to provide an initial introduction to reveal the state of the science around the decision partner concept. In general, the concept analysis offers a vehicle for identifying the shared meaning of related concepts, explaining why those meanings have developed, and describing how a distinct concept can be applied in real-life contexts. It is a strategy to examine the attributes or characteristics of a concept (Walker & Avant, 1994). Through a rigorous process, this concept analysis contributes to a body of knowledge that can help to identify, explore, clarify, validate, and define a concept, as well as clarify overused terms with ambiguous meaning. We aim to identify antecedents, attributes, consequences, and a present definition of the decision partner concept that will add to the understanding of its use in healthcare decision-making.

Methods

Literature Review

A search of relevant health and medical databases, including PsychINFO, PubMed, Embase, and CINAHL, was conducted with the assistance of a reference librarian to identify and clarify the uses, content, and conceptualization of the decision partner concept. The literature search was used to construct conceptual and operational definitions of its defining characteristics and related factors. The following terms were used in the search: decision* NEAR/3 partner*,

decision making, partner, decision support networks, relational autonomy, decision maker, making decisions, adult, family, dyad, interpersonal, decision control, social support, and decision partner, and used in various combinations while conducting the search. Articles from the literature search focused on persons outside of healthcare professionals with whom patients make decisions about care. Inclusion criteria included: English language, human subjects, case studies, systematic reviews, original research and secondary analyses in peer-reviewed journals, and *decision making* whether in the context of health care or treatment decision-making. Research designs included peer-reviewed research studies using mixed-methods, quantitative or qualitative studies as well as review papers focusing on health care decision making. We excluded sources that were not peer reviewed and not published in English, as well as those with unavailable full-texts. The titles and abstracts of the resulting literature were screened to eliminate articles that did not meet the inclusion criteria. Full-text articles were screened to further assess contextual information congruent with the decision partner concept, and articles and reference lists were then reviewed for relevance. The literature search in the presented databases and data selection process resulted in 112 papers included in the concept analysis (Figure 1). Key themes related to decision partner concept were identified and categorized into key attributes that are described later.

Step 1

Search terms: decision* NEAR/3 partner*, decision making, partner, decision support networks, relational autonomy, decision maker, making decisions, adult, family, dyad, interpersonal, decision control, social support, and decision partner

Databases: PsychINFO, PubMed, Embase, and CINAHL

Inclusion Criteria: publications using the term decision partner or some combination of the following terms above

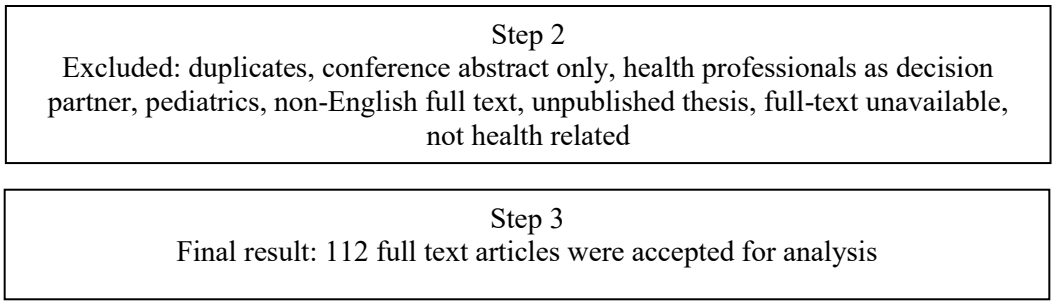

Figure 1 – Literature Review Methods and Results

Methodology

We applied the theoretical approach from Walker and Avant Method (1995) for the concept analysis of decision partner. We chose this method due to its widespread use and its systematic approach. Many authors have successfully used this process in clarifying concepts. Some examples of include Bennett and colleagues (2017) examining the concept of care partner, Kowalik & Yoder (2010) examining decisional involvement, social support examined by several authors (Finfgeld-Connett, 2007; Langford, Bowsher, Maloney, & Lillis, 1997), Hutchfield (1999) examining family-centered care, patient participation examined in the context of a nurse-patient relationship (Sahlsten, Larsson, Sjostrom, & Plos 2008; Cahill, 1996), Chou (2000) examining caregiver burden, and the empowerment concept examined by Ellis-Stoll & Popkess-Vawter, (1998). This form of concept analysis is not a linear activity but rather a circular process, moving back and forth between steps (Kvæl, Debesay, Langaas, Bye, & Bergland, 2018). We identified and presented the eight steps of this method to guide the examination of the function and structure of the concept in Figure 2.

Walker and Avant (2005): The Eight Steps of a Concept Analysis
1. Select a concept.
2. Determine the aims.
3. Identify all uses of the concept.
4. Determine the defining attributes.
5. Construct a model case.
6. Construct borderline, related, contrary, and model cases.
7. Identify antecedents and consequences.
8. Define empirical referents.

Figure 2 – Steps of the Walker and Avant Method for a Concept Analysis.

Findings

Definition

While there are many definitions of the word *decision*, we have chosen to adopt the definition of *decision* as "the act of deciding; a conclusion or resolution reached" (Noone, 2002). Additionally, *decision-making* is defined as the "cognitive process of reaching a decision" (Tariman, Berry, Cochrane, Doorenbos, & Schepp, 2012), and can be stressful as it often involves consideration weighing available treatment, benefits and risks, uncertainty, and the potential for associated burden for patients and important others (Siminoff, 2013; Palmer-Wackerly, Krieger, & Rhodes, 2017). *Partner* is defined according to Merriam-Webster as "one associated with another especially in an action", "one that shares", "a member of a partnership" (Merriam-Webster Dictionary, 2017). The concept of partnership was first used in the context of business and economics, whereby partners assumed an equal share of the profits and losses, as well as participate equally in management (Ying & Loke, 2016). The term *partnership* has since

been extended to the field of health and social care, with the historical emphasis shifting from care providers acting in the role of experts to taking on the role of partners of their clients (Gallant et al., 2002). There is also a growing need to recognize and include third-party members, such as family or close friends, in this healthcare partnership. Partnership refers to "a shared commitment, where all partners have a right and an obligation to participate and all will benefit from the partnership" (Ying & Loke, 2016). The combination of these two definitions of *decision* and *partner* form to create the decision partner concept, which describing someone who shares in the act of making a decision with another person.

Use of Concept in the Existing Literature

The third step in the concept analysis is the identification of the many uses of the concept in literature sources. To date, the decision partner concept has not been commonly used in the literature, see Figure 3. Wenzel et al. (2015) first introduced the term following an analysis of qualitative interviews that revealed the potential influence of family and friends in making patient decision-making about clinical trial participation in their Model of Cancer Clinical Trial Decision Making (Wenzel et al., 2015). Distinct from Wenzel's initial usage, Clayman et al. (2017) expanded the definition beyond clinical trial decision-making to encompass all healthcare related decisions. Clayman and colleagues noted that not all caregivers or family members are engaged in health care decision making and that terms, such as caregivers, should not be conflated with decision partners, whom are engaged in health care decision making (Clayman, Gulbrandsen, & Morris, 2017). Clayman and colleagues recognized that decision partners are essential contributors to patient decisions (Clayman, Gulbrandsen, & Morris, 2017). Lastly, the decision partner concept has most frequently been referred to a significant other (spouse), child, sibling, friend, or close relative (Wenzel et al., 2015; Clayman, Gulbrandsen, & Morris, 2017).

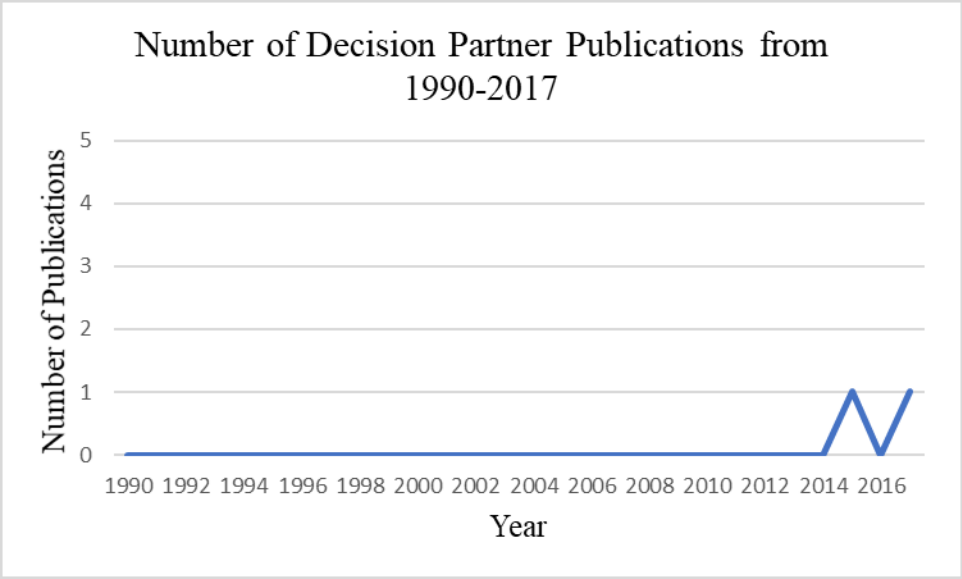

Figure 3 – Number of decision partner publications from 1990-2017.

Defining Attributes

The fourth step in the concept analysis of decision partner is to determine the defining attributes. Defining attributes are characteristics of the concept that appear repeatedly in the literature, and they are most frequently associated with the concept allowing the broadest insight into it (Walker & Avant, 2011). Defining attributes are associated with the concept and differentiate the concept from related concepts (Bennett, Wang, Moore, & Nagle, 2017). The six defining attributes of the decision partner concept are found in Table 1 and include: (1) having a trusting relationship with the patient, (2) demonstrates a willingness to participate in decision-making, (3) articulates a clear understanding of both the patient's health condition and the decision that must be made, (4) demonstrates decision-making self-efficacy, (5) exemplifies an emotional capacity to participate in decision-making, (6) willingness to fulfill several supportive roles as needed.

(1) *Has a trusting relationship with the patient.*

The first attribute of a decision partner is that he or she must have a trusting relationship established with the patient. With having a trusting relationship with the patient, there is an assumption that the decision partner has perceived knowledge of the patient and can be either a family member, close friend, spouse or cohabitating partner or significant other to the patient.

(2) *Demonstrates a willingness to participate in decision-making*.

The second attribute of a decision partner is that he or she has a willingness to be a part of the health care decision-making process with the patient. The decision partner must have a desire to participate, question, challenge and seek information. He or she does not necessarily be physically present or in close proximity with the patient but must be available and accessible.

(3) *Articulates a clear understanding of both the patient's health condition and the decision that must be made.*

The third attribute of a decision partner is that he or she must be able to articulate a clear understanding of both the patient's health condition and knowledge about the decision that must be made in order to adequately contribute as a decision partner. He or she should bring personal knowledge on the suitability of different treatments for the patient's circumstances and preferences (McGinnis et al., 2013), and provide the doctor with information about the patient's medical history or symptoms (Wolff, Clayman, Rabins, Cook, & Roter, 2012). This understanding allows the decision partner to engage in decision-making fully and responsibly in a way that optimally benefits the patient.

(4) *Demonstrates decision making self-efficacy*

The fourth attribute of a decision partner to exhibit self-efficacy in decision-making. It is well-understood that it can be difficult to sort through an overwhelming amount of information and identify the facts that are relevant to the choice in question (Rid & Wendler, 2010).

Therefore, decision partners should also be able to demonstrate decision making self-efficacy in their role. Self-efficacy refers to individuals' beliefs regarding their capability to produce designated levels of performance that exercise influence over events (Lopez & Guarino, 2013). According to the Surrogate Decision Making Self-Efficacy Scale (SDM-SES), components of self-efficacy for decision making include (1) knowing when to make decisions, (2) ability to obtain information to make informed decisions, (3) ability to weigh risks and benefits of treatment options, (4) ability to make the best treatment decisions, and (5) knowing what treatment options the individual patient would select (Lopez & Guarino, 2013). Decision-making self-efficacy includes an assertiveness and confidence to openness discuss the health care decision options with the patient and medical team.

(5) *Exemplifies an emotional capacity to participate in decision-making*

The fifth attribute of decision partners include having an emotional capacity to participate in decision-making (Zeliadt et al., 2011). One study found that a major factor in what family members want to hear or can absorb is, of course, their emotional state (Billings, 2011). Shock and denial are common reactions to distressing information, even when family members think they are prepared (Hebert, Dang, & Schulz, 2006) or when the [bad] news seems to clinicians like an obvious culmination to a serious chronic illness (Billings, 2011). There can be emotional discomfort, including intrapersonal tensions and inner emotional conflicts (Jezewski, 1994), especially when one must make 'life or death' decisions (Schenker, Crowley-Matoka, Dohan, Tiver, Arnold, & White, 2012). Therefore, decision partners exhibit traits of being emotionally-ready to participate in decision-making.

(6) *Willing to fulfill several supportive roles as needed.*

The sixth attribute of a decision partner is being able to fulfill a variety of supportive roles as needed for the patient during the decision-making process. Roles may include serving as the patient advocate by defending the patients' interests, giving useful information and asking questions to know more about the treatments (e.g. alternatives, potential benefits/consequences) (Lamore, Montalescot, & Untas, 2017). The decision partner may also serve as the 'hub of information' for the patient, which means to gather information about a decision that must be made as well as obtain shared information and knowledge about the patient (Reeves et al., 2015). This role also entails obtaining the patient's opinion, expectations, and experiences and providing individually adapted information/knowledge (Eldh et al., 2004; Henderson, 2002; Sainio, Lauri, & Eriksson, 2001; Sainio & Lauri, 2003; Tutton, 2005; Sahlsten et al., 2008), acting as a 'messenger' or 'middleman' (Laidsaar-Powell[c], Butow, Bu, Fisher, & Juraskova, 2016), and translating and passing on information to other family members (Quinn et al., 2012) who are present or outside of the medical encounter. Their role may also include summarizing the information given by the clinician, and repeat or filter information (Lamore, Montalescot, & Untas, 2017; Laidsaar-Powell et al., 2016[b]; Laidsaar-Powell et al., 2016[c]), and acting as a surrogate decision maker or translator (Reeves et al., 2015).

Model, Borderline, and Contrary Cases

To contribute to the decision partner concept analysis, model, borderline, and contrary examples can be used (Walker & Avant, 2011). We presented these examples below to provide a better understanding of decision partner, given the multiple defining attributes of the concept.

Model Case

A model case example is one that includes all defining characteristics of the concept. In the case of Lee, a 44-year old single father of two, he was recently diagnosed with cancer and

had an upcoming appointment with his new oncologist. Lee decided to invite one of his adult daughters to accompany him on the visit and help remind him to ask certain questions. Lee's daughter, Sarah, does not live close by and made a special trip to accompany him on the visit. However, her father regularly calls her on the phone to include her in the medical visits and discussions about decision-making. In her role as a decision partner, Sarah provides the clinician with detailed information related to her father's medical history and weighs in about different treatment options that are presented to him. Sarah knows her father well. She helps him to process information, discusses the risks and benefits involved, as well as provides support and encouragement. She often asks questions to the medical team and communicates with her sister following each visit in order to update her on the health care decisions as well. This is an example of a model case of the decision partner concept.

Borderline Case

A borderline case is where the use of the concept has some but not all concept characteristics (Walker & Avant, 2011). In the case of Jim, he is an elderly patient with type 2 diabetes who was admitted to the hospital following an acute stroke. Jim is slowly recovering from the stroke and has recently appointed his adult son Jarrett as his medical power of attorney. Although Jarrett lives across the country and talks to his father a few times a year, he still considers himself to have a fairly good relationship with Jim, although at times their relationship is estranged. Jarrett often does not feel knowledgeable enough to make decisions with the medical team, he is emotionally withdrawn, and having difficulty coping with his father's health condition. This case is a clear example of what it means to lack vital attributes of a decision partner, including a willingness to fulfill supportive roles as needed, exemplify an emotional

capacity, demonstrate decision-making self-efficacy, and articulate a clear understanding of her father's health condition and the decision that must be made.

Contrary Case

A contrary case is one where the concept of decision partner is used contrary to the identified attributes of a decision partner. In the case of Stacy, she is a 39-year old female patient with uncontrolled hypertension and kidney failure. Stacy was recently admitted to the acute inpatient unit following a risky surgery. After surgery, she faced several complications, including an uncontrolled blood pressure, increased fluid retention, and a rise in her electrolyte levels. Her disabling condition is critical, yet Stacy does not have legal documents such as a living will to cover decisions about her health matters. She has been assigned a court-appointed legal guardian for her health-related matters. The role of her court-appointed legal guardian, Larry, is to make decisions, give consent to health-related decisions, and facilitate communication between health care provider and patient, though not acting as a decision partner for Stacy. Larry knows very little about her medical history, social history, and current health condition, and he is neither family nor friend. Larry does not necessarily advocate for treatment-related goals that are based on Stacy's personal preferences and values, nor does he communicate regularly with Stacy or her family to better understand her goals of care. A health-related decision must be made about her plan of care, but it is important to discern whether Larry has adequate information to arrive at a decision and whether he is making these decisions in her best interests. This is an example of a contrary case of the decision partner concept.

Related Concepts

A related concept is identified as a concept that is related to the decision partner concept does not exhibit all of the defined attributes.

1) *Decision-support person, decision-support networks, partner decisional support*

Decision-support persons, decision-support networks, or partner decisional support are inter-related and are often seen in the literature as family and friends who contribute to treatment decisions made by patients and are considered to be both important and influential (Wallner et al., 2017). Decisional support is defined as social support given and received during a decision-making context (Krieger, 2014; O'Connor, 2006; Milata, Otte, & Carpenter, 2018). In a study by Palmer-Wackerly and colleagues (2017), it was found that partner decisional support may partially mediate the relationship between health care provider (HCP) support and patient decision-making satisfaction. Decisional support is different from other definitions of social support that focus on the quantity, frequency, structure, and availability of perceived social support (Goldsmith, 2004; Palmer-Wackerly, Krieger, & Rhodes, 2017). These related concepts differ from decision partner in that decision partners are involved more broadly in health care decisions, not just specifically treatment decision-making.

2) *Carer*

Similar to decision partners, carers can also facilitate the process of deliberation by obtaining information about treatments, discussing information with the patient, eliciting information from clinicians, and act as sounding boards for the patient to help stimulate thinking about treatment decisions and processes behind the scenes (Hubbard et al., 2010). However, their primary roles are not related to decision-making. In the literature, carers have been largely defined as those persons who provide assistance, and are frequently spouses, siblings, children, other relatives, or friends (Bennett, Wang, Moore, & Nagle, 2017). They are seen as providing the majority, if not all, of the care for a person who is unable to independently manage their own care and activities of daily living (Bennett, Wang, Moore, & Nagle, 2017). Carers have also

been described as “hope carriers”—as those who remain hopeful even when those they are caring for feel hopeless (Bradley & Green, 2018; Marshall, Deane, Crowe, White, & Kavanagh, 2013).

3) *Caregiver*

Caregiver is commonly defined as a person who has a close relationship with the patient and provides assistance with the coordination of care, symptom management, disability, mobility, medications, and dressing (Lim & Zebrack, 2004; Bennett, Wang, Moore, & Nagle, 2017). In her analysis of the concept of empowerment of family caregivers, Sakanashi et al. (2017) described how engagement in health care decision making was one dimension of empowerment of caregivers.

4) *Care partner*

The defining characteristic of the care partner concept is the existence of a person with a health condition requiring some assistance with health care needs (Bennett, Wang, Moore, & Nagle, 2017). The term *care partner* recognizes the interdependent and often reciprocal relationship between two or more persons who enact caring roles towards one another (Womack, Isaksson, & Lilja, 2016). Care contexts range from acute medical needs to long-term and end-of-life care (Bennett et al., 2017). Care partners are predominantly family members, frequently the spouse, cohabitating partner, or those persons who are in a romantic relationship with the patient (Bennett et al., 2017; Rini et al., 2011; Manne et al., 2012), and refer to individuals who function in unpaid or informal roles (Womack, Isaksson, & Lilja, 2016). They can provide ADL support to high level care, assist with health care information facilitation, medical appointment coordination, hospital care assistance, monitoring vital signs, home care assistance, coordination of community and government assistance, coordination of family member involvement, administration of medications, and transport (Bennett, 2017). In comparison, the role of decision

partners has been a component of the analysis of broader concepts such as care partners (Bennett, 2017) and parent participation (Vasli, 2014).

5) *Study partner*

Previous investigators had used the term *study partner* to refer to family members, friends and others who participated in patients' decision to enroll in a clinical trial and noted that some study partners became participants in the study themselves, thereby adding some confusion to the role (Black, Taylor, Rabins, & Karlawish, 2014; Karlawish, Kim, Knopman, Dyck, James, & Marson, 2008). Researchers have described the role of study partner as an *informant* for the patient-subject, and a decision-maker either as a surrogate for subjects who lack decisional capacity or a participant in joint decision-making with those who are less cognitively impaired (Black, Taylor, Rabins, & Karlawish, 2014; Grill, Monsell, & Karlawish, 2012). Their responsibilities include managing the logistics of study participation and provide comfort and encouragement for the patient-subject (Black, Taylor, Rabins, & Karlawish, 2014). They differ from decision partners in that they specifically focus on clinical trial-related decisions and have been described to be involved in decision-making with patients with cognitive impairments, while decision partners are involved in a wider range of health care decisions.

6) *Close other*

Close others can be defined as individuals such as a partner, family, and friends who patients seek out for advice and comfort (Rini et al., 2011). More simply, Acar-Burkay and colleagues define close others as close friends (2017). In other literature, close others have been referred to as romantic partners (Etcheverry & Agnew, 2008), family and friends (Hughes & Dunn, 2002), and close friend (Rosa & Gutchess, 2011). Close others differ from decision

partners in that their role is not explicit to a particular action such as decision-making or caregiving.

7) *Surrogate or proxy decision maker*

Surrogates are typically family members who are entrusted with the authority to make health care decisions for decisionally incapacitated patients, and patients who are too ill (Schenker et al., 2012), unable to express their treatment preferences (Majesko, Hong, Weissfeld, & White, 2012), have progressive cognitive impairment (Elliott et al., 2009; High & Rowles, 1995) and those who are dying (Dionne-Odum et al., 2015). Surrogates differ from decision partners in that they often make decisions in the absence of the patient's input. They are expected to make decisions that approximate as closely as possible the choices patients would make were they able (Beauchamp & Childress, 2012; Dionne-Odum et al., 2015; Winter & Parks, 2008).

8) *Accompanying person or companion*

In the literature, an accompanying person (AP) is defined as a family member or close relative who is present in a clinical consultation when information is shared between doctor and patient (Lee, Teo, & Kanesvaran, 2018; Andrades, Kausar, & Ambreen, 2013). An AP has also been described elsewhere (Ekwall, Gerdtz, & Manias, 2009), in the context of emergency room visits, as the individual who plays a vital role in delivering psychosocial support to the patient. The primary role (68.6%) of an AP is to be a patient advocate, as Botelho et al. (1996) describes in their work examining behavior and preferences of patients regarding family involvement in routine health care visits. Similar to an AP is the term *companion*. Companions accompany patients to the medical visit and can help patients provide physicians with essential medical history as well as reinforce, verify, and augment patients' statements (Street & Gordon, 2008; Clayman et al., 2005). Companion behaviors were broadly categorized in relation to enhancing patient autonomy: (1) facilitating doctor understanding, (2) facilitating patient understanding, (3)

facilitating patient involvement (Wolff, Clayman, Rabins, Cook, & Roter, 2012). Alternatively, autonomy detracting behaviors were also identified and include (1) controlling actions towards the patient as well as (2) alliance building with the doctor (Wolff, Clayman, Rabins, Cook, & Roter, 2012). In comparison, the companion or AP may or may not be involved in decision-making, while DPs are involved. Predominantly, their role is to be a supportive physical presence for the patient, which is not necessarily true for DPs who are sometimes not able to be present with the patient.

Identification of Antecedents and Consequences

The seventh step in the concept analysis is the identification of antecedents and consequences (Walker & Avant, 2011). Antecedents are factors that are required for the concept to occur and exist (Bennett, Wang, Moore, & Nagle, 2017). Antecedents for the concept of decision partner are both practical and behavioral factors that span across different health conditions and diseases. The consequences of the decision partner concept, for patients, families, clinicians, and healthcare organizations, are evident. Introducing and implementing this concept can impact the way in which the healthcare system includes the role of others in healthcare decision-making and emphasize the unique contribution they often bring to the decision-making process.

Antecedents of the Decision Partner Concept:

1) *There is a health care decision that must be made.*

First, in order for the decision partner concept to exist, there must be a health care decision that must be made. More specifically, there must be more than one option from which to choose.

2) *There is an established trusting relationship between the patient and the decision partner.*

Secondly, the concept of decision partner requires an established trusting relationship with the person who has to make a health-related decision. Trust is indispensable to all social relations (Acar-Burkay, Fennis, & Warlop, 2014) and is defined as an individual's willingness to accept vulnerability based upon positive expectations of the intentions or behavior of another (Rousseau, Sitkin, Burt, & Camerer, 1998). In addition, trust can also be defined as the reliance on others (Gonzalez, 2017; Mieize-Growchowski, 1984). At the interpersonal level, trust enhances cooperation (McAllister, 1995) and information sharing (Butler, 1999), which is critical in decision-making (Acar-Burkay, Fennis, & Warlop, 2014).

3) *The patient perceives and recognizes the decision partner as an essential contributor in decision making.*

Thirdly, in order for the decision partner concept to exist, the patient who is making a health-related decision should perceive and recognize the decision partner as important, in many cases, essential contributors to patient decisions and their desire and capacity to follow through on managing the plans made (Clayman, Gulbrandsen, & Morris, 2017). This antecedent is critical to the concept because it focuses on the notion that the patient values and cares about the opinion of another.

4) *The patient has a participatory style of decision making.*

Patients who have intact decision-making capacity vary considerably in their decision control preferences (Nolan et al., 2007). Some prefer to make decisions independently, while others prefer to defer decision-making authority to loved ones or physicians, and most would opt for shared decision-making (Nolan et al., 2007). For the decision partner concept, it is important to establish an understanding of the patient's preferred level of decision partner involvement in decision-making so that roles and expectations are well-considered.

Consequences of the Decision Partner Concept:

The consequences of introducing the decision partner concept include:

1) *Broad enough to include non-family decision partners*

The decision partner concept is broad enough to include family and non-family decision partners because health care decisions will undoubtedly impact their lives as well. John Hardwig stated in the Hastings Center Report (1990) that there is no way to detach the lives of patients from the lives of those who are close to them. He described "family" means "those who are close to the patient", and often includes close friends and companions, recognizing that the word "family" has many meanings (Greogry, 2004).

2) *Confusion about whether this concept refers to health professionals or lay persons.*

There is potential confusion about whether this concept refers to or can also include health professionals in addition to lay persons. For instance, information giving has been an essential part of the nurse's role in clinical practice, as does promoting patient autonomy and advocacy (Tariman & Szubski, 2015). However, it is important to note that decision partners are selected by the patient and must have a relationship and be knowledge about the patient in order to be engaged in decision-making, which is not necessarily true regarding health professionals.

3) *There is potential for decisional conflict in healthcare decision making.*

When decision partners are present in healthcare decision-making, there is potential for discordant views on the decision that must be made. Individuals may place different values on different outcomes related to the decision or may enter into a clinical consultation with different goals (Lee, Teo, & Kanesvaran, 2018). For example, the patient may want to obtain a clear understanding of the disease condition and the decision partner may be seeking the best treatment. While the decision partner may have an impact in helping the patient make decisions

and provide emotional comfort and psychological support (Lin, Huang, & Chen, 2017), there are instances when disagreement can arise between the patient, decision partner, and clinician. Certain behaviors may also be exhibited including nagging, trying to take control of the decision, or acting angry or disapproving. They could also be planning to set and promote their own agenda instead of that of the patient (Street & Gordon, 2008; Heid, Zarit, & van Haitsma, 2016). In a study investigating the full "triad" of patients, oncologists, and caregivers in cancer treatment decision-making, LeBlanc and colleagues (2017) found that patients, caregivers, and oncologists have significantly different preferences about both treatment decisions and the decision-making process. The researchers found that triad members frequently disagreed about the "correct" treatment choice (LeBlanc et al., 2017). These divergent opinions (Rini et al., 2011), values and priorities could counter patients' autonomy and best interests (Ho, 2008), and their decisions may not accurately reflect patient's values and result in discordant preferences (Vig et al., 2007; Schenker et al., 2012; de Boer et al., 2015; Shin et al., 2015).

4) *There is potential for patients to have more than one decision partner*

Often families have multiple decision makers rather than one primary decision maker as preferred by the clinicians (Quinn et al., 2012), and each person may play a different role in the decision-making process. Subsequently, the need to consider the wishes of other family members may pose a barrier to clear decision-making (Parks, Winter, Santana, Parker, Diamond, Rose, & Myers, 2011), thereby making decision-making more difficult (Schenker et al., 2012). Multiple decision partners may result in multiple individuals asking a lot of questions (Coats et al., 2018), and requiring the medical team to divide their attention between the patient and family. Recognizing and understanding the roles of multiple decision partners during critical decision

making is important in facilitating more effective interaction and consensus among family members and reducing conflict among family and clinicians (Quinn et al., 2012).

5) *Emotional and psychological burden related to decision-making*

The decision partner concept can also result in increased emotional and psychological burden for potentially the patient, clinician, and decision partner in different ways. The patient may report emotional and psychological burden about involving a third-part, *an additional person*, in the decision-making process as well as express feelings of not wanting to disappoint the decision partner in the decision that was made. Secondly, the clinician may recognize decision partners as 'important', 'essential', 'critical', or 'imperative' (Laidsaar-Powell et al.[a], 2016), but challenges can arise when they become controlling, dominant, manipulative, or requesting non-disclosed information. Acknowledging family members' interests would bring benefits as well as burdens to medical practitioners (Hardwig, 1990). Decision partners may suffer from emotional and psychological burden as well. Feelings can include feeling burdened, (Wendler & Rid, 2011; Braun, Naik, & McCullough, 2009; de Boer et al., 2015), and stretched beyond their capacity (Holroyd-Leduc et al., 2016). They may also feel a sense of grief, anxiety, stress, guilt as well as doubt regarding whether they had made the right decisions (Wendler & Rid, 2011). In addition, they may find difficulty in making decisions under a time pressure (de Boer et al., 2015). In the context of surrogate decision-making, Swigart, Lidz, Butterworth, & Arnold (1996) reported that surrogates repeatedly "searched their own sense of morality" about making decisions that could be life-threatening. Therefore, it is important to recognize the emotional and psychological burden that all stakeholders may face.

6) *Promotion of incorporating patient preferences*

The presence of decision partners may allow for more opportunity to focus on patient goals and values for health care decisions. They may help to prioritize goals of care in line with the values and preferences of the patient (de Boer et al., 2015), relay the patients' questions and concerns to the physicians and vice versa (Lamore, Montalescot, & Untas, 2017; Lin, Pang, & Chen, 2013) and help during the consultations when the patients are distressed (Lamore, Montalescot, & Untas, 2017; Lin, Huang, & Chen, 2017). Their presence could consist of helping patients in seeking, organizing, and processing information for health decisions, including finding a health care provider, receiving advice about treatment, and describing symptoms to providers (Krieger et al., 2015; Siminoff et al., 2006; Palmer-Wackerly, Krieger, & Rhodes, 2017).

7) *Increased patient engagement in decision-making*

The presence of decision partners could result in increased patient engagement in decision making. Studies have found that family involvement in patient care enhances patient's autonomy rather than detract from it (Shin et al., 2013; Clayman, Roter, Wissow, Bandeen-Roche, 2005), and has been associated with greater question-seeking, less passive agreement with physician information, less social talk, and more orienting statements (Wolff, Clayman, Rabins, Cook, & Roter, 2012). Family involvement has been shown to support patient engagement particularly for vulnerable patients such as those who are older, less literate, mentally or cognitively impaired, who have sensory or functional deficits, or who must manage complex treatment regiments (Wolff, Clayman, Rabins, Cook, & Roter, 2012; Katon, 2008).

8) *Emphasis on relational autonomy*

The decision partner concept constitutes a shared approach to decision-making that draws on the guidance of others—the essence of relational autonomy. The concept of relational

autonomy occurs when individuals work alongside those they are in close relationships with, seeking compromises that are good for 'us' rather than weighing up competing interests (Skyrme, 2016). When considered as an individualized quality that is disassociated from relational contexts, autonomy fails to account for joint decision-making (Carnevale, 2012). Hence, the decision partner concept places emphasis on relational autonomy, which recognizes the importance of social circumstances and significant relationships on individuals' self-determination (Bell &Balneaves, 2015; Beauchamp & Childress, 2012; Sherwin, 1998).

9) *Loss of privacy for patients*

A challenge with the decision partner concept is the issue of maintaining patient privacy (Laidsaar-Powell[c], Butow, Bu, Fisher, & Juraskova, 2016) and recognizing patient feelings of discomfort about involving others in decision-making and sharing personal medical information in discussions. When given access to private health-related information, the decision partners become co-owners of someone else's information (Bute, Petronio, & Torke, 2015). Alternatively, it is also important to recognize the current emphasis on privacy and confidentiality in today's health care, which may make decision partner roles more challenging.

10) The decision partner is not well-informed about the decision that must be made.

It can also be a possibility that the decision partner is not well-informed about the decision that must be made. When this happens, it can impact the patient's decisions and diminish the contributions of the decision partner in the decision-making process.

Table 1 – Decision Partner Concept Components

Antecedents	Attributes	Consequences
1. There is a healthcare decision that must be made by the patient.	1. Has a trusting relationship with the patient.	1. Broad enough to include non-family decision partners.
2. There is an established trusting relationship between the patient and the decision partner.	2. Demonstrates a willingness to participate in decision-making.	2. Potential confusion about whether this term refers to health professionals or lay persons.
3. The patient perceives and recognizes the decision partner as an essential contributor.	3. Articulates a clear understanding of both the patient's health condition and the decision that must be made.	3. Potential for decisional conflict in healthcare decision making.
4. The patient has a participatory style of decision making.	4. Demonstrates decision-making self-efficacy.	4. Potential for patients to have more than one decision partner.
	5. Exemplifies an emotional capacity to participate in decision-making.	5. Emotional and psychological burden related to decision-making.
	6. Willing to fulfill several supportive roles as needed, including patient advocate and the "hub of information".	6. Promotion of incorporating patient preferences
		7. Increased patient engagement in decision making
		8. Emphasis on relational autonomy
		9. Loss of privacy for patients
		10. The decision partner is not well-informed about the decision that must be made.

Empirical Referents

The eighth and final step in the concept analysis is the identification of the empirical referents. These are classes or categories of actual phenomena which by their existence or presence demonstrate the occurrence of the concept itself (Wahlin, 2017) by providing specific measurable examples to verify the presence and subsistence of the concept (Walker & Avant, 1995). In the current literature, we have not been able to identify any empirical referents for measuring the effect, existence, or attributes of the decision partner concept. Currently, there are existing instruments of related concepts of perceived social support (PSS) using the family subscale (PSS-FA) and friends subscale (PSS-FR) (Glozah & Pevalin, 2017; Procidano & Heller, 1983), and decisional support (Palmer-Wackerly, Krieger, & Rhodes, 2017).

Discussion and Recommendations

Increasingly, a more inclusive philosophy of care that encompasses the importance of including the decision partner in health care decision making is needed. This concept analysis may be a helpful first step in that direction. The decision partner concept emphasizes the contribution that all stakeholders make to the patient's decision-making, recognizing that each person involved is an expert in their own right. From an ethical standpoint, the decision partner concept is supported by the principle of relationality that posits that human beings are intrinsically related to others and are members of communities (DuBois, 2007). In addition, understanding decision partners in healthcare decision-making has policy and practice implications. Incorporating decision partners could transform the way in which health services deliver collaborative and integrated care across systems; conducting evidence-based research that includes patients and decision partners as equal partners is important to fully understand healthcare decision-making. The engagement of decision partners represents an important patient

value as well as a potential source of support or conflict in the decision-making process. Decision partners have the potential to recognize and acknowledge the choices that are most patient-centered by reflecting on the patient's individual preferences and health outcomes and goals. As a result, their role could potentially improve patient adherence, compliance, and understanding about their health condition, which in turn, can result in better health outcomes, greater patient satisfaction (Joosten et al., 2008), as well as reduced health care costs (Chi, Wolff, Greer, & Dy, 2017; O'Connor, Bennett, Stacey, et al., 2009; Arterburn et al., 2012; Elwyn, Frosch, & Kobrin, 2015).

There are key recommendations that may suggest ways to use and apply the decision partner concept in reshaping research, practice, and policy. First, a culture of research that involves patients and their decision partners must be embedded in academic curricula of health professionals and researchers and implemented in practice. In today's health care, it is important for clinicians to not assume that patients make decisions in isolation. Therefore, it is imperative to develop and integrate decision partner engagement data and to direct attention to decision partners themselves for continuous improvement related to health care systems and community health-based programs. Furthermore, establishing and maintaining workforce capacity building that supports decision partner engagement is necessary to improve training and research efforts to improve decision partner engagement. Second, there must be attention to identifying ways to support patients who are able to identify a decision partner as well as those who cannot. Additionally, although patients may identify a decision partner, it is imperative that patients and decision partners still feel like they have access to members of the care team in order to optimize health outcomes and satisfaction with care.

Third, future research is needed to measure and describe the relationship that decision partners have with patients, and clinicians, and with each other as they engage in decision-making. These measures can support better understanding of the triadic relationships between patients, decision partners, and clinicians. Fourth, patient outcomes associated with decision partners should be examined including quality of life, healthcare utilization, treatment costs, effectiveness of care, satisfaction with care, medical errors, readmission rates, timeliness of care, integrated care and transitions of care, and mortality rates. These outcomes could be examined for differences when decision partners are engaged in decision making compared to when decision partners are absent. Measures and observations are needed to assess what patient characteristics predict or warrant the need for a decision partner, and interviews may help to understand reasons why some patients may not have a decision partner present while other patients do not. Fifth, future family communication interventions could explore ways to support patients and decision partners in communication surrounding shared illness experiences while respecting patients' desire for their involvement. As patients' health needs grow increasingly more complex, focusing on coordination and communication across all of a patient's health care providers is even more crucial (McGinnis et al., 2013), as well as finding ways to incorporate decision partners. There is also a dearth of information related to how the role of decision partners vary across different cultures and geographic regions of the world that needs to continue to be explored. Sixth, decision partners need clinician support in order to be well-integrated in health care systems, community programs, policy reform, and public health initiatives related to healthcare decision making. Nurses are central to health care, working closely with patients, their support networks, and communities. This positions nurses well to acknowledge, advocate for, and involve decision partners in health care decision making. Family nurses, in particular, can

take an active role in policy and leadership not only in health care but in social policy that covers the gamut of human concerns (Grady & Hinshaw, 2017).

Conclusions

It is important to support and further explore dimensions of decision partners, describing how they may be deeply rooted within complex relational dynamics of patients that could potentially impact health care decision-making, satisfaction with care, health outcomes, treatment adherence, self-management practices, and sharing of information that helps clinicians better elicit, understand, and respect patient perspectives and preferences. With a dearth of knowledge in the current literature about decision partners, we aimed to explicitly define and describe their role and how their contributions may influence decisions. It is essential for nurses and other clinicians to identify and understand the role of decision partners in the context of health care decision-making, particularly as engagement of decision partners requires a shift in the traditional culture of healthcare and shared decision-making between patients and providers.

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CHAPTER IV: Manuscript Two: Quantitative Study Results

This chapter, focused on the quantitative study results, is the second of three manuscript papers that comprises this dissertation. It is the authors' intent to submit this article to Patient Education and Counseling. There is a required format for this journal submission, which includes a title page, abstract, introduction, methods, results, discussion and conclusion, references, and legends. The word limit for research papers is 4000 words. The manuscript word count excludes the following: abstract, acknowledgments, references, tables, figures, and conflict of interest statements. This journal accepts descriptive studies, which is the design of this dissertation study. The subheading that best identifies which section of the journal this manuscript belongs to is the subheading of Patient and User Perspectives and Characteristics. Within the text, references are indicated by number(s) in square brackets in line with the text. The actual authors can be referred to, but the reference number(s) must always be given. Reference citations should be numbered consecutively throughout using Arabic numerals in parentheses or square brackets, double spaced, and start on a separate page. The journal requires a structured abstract, by means of appropriate headings (objective, methods, results, conclusion, practice implications), and should provide the context or background, purpose, basic procedures, main findings, conclusions, and practice implications. The abstract is limited to 200 words.

Title: Factors Influencing Outpatient Adult Cancer Patients' Decision Making about Clinical Trial Participation and their Preferences to Involve Decision Partners

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Abstract

Objective: To describe the relationships between Patient Factors (Decision Control Preferences, Age, Gender, Education, Marital Status, Race, Ethnicity), Clinical Trial Knowledge, Attitudes, and Beliefs, and Clinical Trial Participation (CTP).

Methods: Adult cancer patients (n=82) were recruited from a parent study in the mid-Atlantic region of the United States. Patients screened as having an available clinical trial. Patient and decision partner demographics were collected, as well as cancer type, DCP, and patients' clinical trial knowledge, attitudes, and beliefs. We performed descriptive statistics, bivariate analyses, and t-tests to assess for differences and associations. Linear regression analyses were conducted to assess predictors of clinical trial knowledge, attitudes, and beliefs.

Results: Among those who were offered a clinical trial (n=21), there were no statistically significant associations between race, caner type, gender, marital status, education, and CTP. Women tended to have higher scores related to knowledge, attitudes, and beliefs about clinical trials (p=0.022), even after controlling for education level and race. We did not have sufficient patients being offered clinical trial participation to be able to measure associations between DCP and CTP.

Conclusion: Future studies should include larger and more diverse samples of participants who are offered a clinical trial to further understand the influences that decision partners have on clinical trial decision making.

Practice Implications: Recruitment into cancer clinical trials can be successful, but there are still many barriers and patient level factors which must be taken into account.

1. Introduction

Progress in prevention and control of cancer depends on research that identifies treatments that prevent or delay death caused by cancer or improve quality of life for patients living with cancer (Kanarek, Tsai, Metzger-Gaud, Damron, Guseynova, Klamerus, & Rudin, 2010). Clinical trials serve the overall population by determining the safety and efficacy of potential medical treatment (Jimenez, Zhang, Joffe, Nisson, Rivera, Mutchler, Lathan, Paulk, & Prigerson, 2013). Clinical trials can also be beneficial to participants themselves by giving them the opportunity to receive professional care and possibly to gain the benefit of new treatments before they are available outside of trials (Brown & Moyer, 2010). Enrollment of American cancer patients in clinical trials has remained modest despite significant progress in cancer care as well as the federal government's own decades (Jimenez, Zhang, Joffe, Nisson, Rivera, Mutchler, Lathan, Paulk, & Prigerson, 2013). Low participation rates may stem from potential participants lacking an understanding of medical research studies, or it may result from a lack of vested interest in the condition or treatment under investigation if they are healthy or do not have personal experience with it (Brown & Moyer, 2010; Gillis et al., 2001). In this article, we are exploring the social as well as demographic factors that may shape how individuals make decisions.

1.1. Specific Aims and Hypotheses

Aim 1: To describe the relationships between Patient Factors (Decision Control Preferences, Age, Gender, Education, Marital Status, Race, Ethnicity), Clinical Trial Knowledge, Attitudes, and Beliefs, and Clinical Trial Participation.

Hypothesis 1.1: Individual patient factors are associated with clinical trial participation.

Lower educational attainment will be associated with decreased participation in a clinical trial. Younger age will be positively associated with clinical trial participation.

Hypothesis 1.2: Knowledge, attitudes and beliefs will be associated with clinical trial participation.

An increased clinical trial knowledge level and more positive attitudes and beliefs about clinical trials will be positively associated with a patient's decision to participate in a clinical trial.

Hypothesis 1.3: Educational level will be associated with decision control preference. *Higher education level will be associated with a higher level of decisional control preference.*

Hypothesis 1.4 Decision control preferences will be associated with clinical trial participation. *Preferences for a more deferred decision style will be positively associated with patient's decision to participate in a clinical trial.*

2. Methods

2.1. Setting and Recruitment

Data collection occurred over a 24-month period from March 2016 to March 2018. We recruited study participants were recruited from an outpatient clinic within a large comprehensive cancer center in the state of Maryland, within the mid-Atlantic region of the United States. Participants within this study had already consented and enrolled into a parent study, the EMPaCT Patient Navigation Study, which focused on evaluating the effectiveness of a patient navigation program to increase recruitment and retention into cancer clinical trials. Since the patients were already consented and enrolled into the parent study, the inclusion criteria were similar to the inclusion criteria of the parent study. Inclusion criteria included that the patients had completed the Control Preference Scale, had a primary tumor cancer diagnosis (breast, prostate, multiple myeloma, ovarian, endometrial, head and neck), were screened to have an

available therapeutic cancer clinical trial as identified through medical record review and a specific content expert-derived screening algorithm created by research nurses and oncologists at the study site, had residency in the state of Maryland, aged 18 years and older, and were able to read, write and understand English. Exclusion criteria included primary residence outside of Maryland, medical record review did not identify an available therapeutic cancer clinical trial, and unable to read, write and understand English. All adults who are screened for an available therapeutic cancer clinical trial were contacted by phone prior to the scheduled medical oncology visit by either the author of this paper or the patient navigator of the parent study. The goal of this pre-visit call was to introduce and determine patient interest in participating in the parent study. Following the protocol of the EMPaCT parent study, participants received no financial compensation for their participation in completing the study.

The parent study had sought and obtained full Institutional Review Board (IRB) approval from Johns Hopkins Medical Institutions (JHMI) (NA_00072282). For this study, addenda were incorporated and approved by the IRB to approve additional study measures obtained outside of the parent study. In order to find potential patients who may be eligible for cancer clinical trials, and therefore the parent study, the study team reviewed the electronic medical records. On the day of the oncology visit in the outpatient clinic, the patient navigator or first author of this paper approached the patient in the outpatient clinic waiting area with the goal of meeting with them prior to their encounter with the oncologist to discuss the study. Patients had the opportunity ask questions and were informed that participation in the study was voluntary. A written informed consent was obtained for the study.

2.2 Measures

All participants completed an initial assessment and questionnaires to ascertain sociodemographic data (age, race, ethnicity, gender, highest level of educational attainment, marital status), decision control preferences, as well as an assessment measuring clinical trial knowledge, attitudes, and beliefs. The outcome variable was the decision made about clinical trial participation (yes, no, not offered/delayed offer). The outcome variable was determined based on whether patients received an offer to participate in a therapeutic cancer clinical trial. Participants completed the questionnaires independently or with assistance from research team members.

2.2.1. Sociodemographic Factors

Patients reported their age, gender, highest level of educational attainment, marital status, race, and ethnicity. Sociodemographic factors are those modifiable and unmodifiable patient and decision partner characteristics that may influence the decision regarding cancer clinical trial decision-making. Sociodemographic factors are socially constructed and have been shown to be predictors or characteristics of cancer patients who participate in clinical trials. The categories for gender included male and female. The categories for race were: African American or Black, White, Asian or Asian American, American Indian or Alaska Native, and Native Hawaiian or Pacific Islander, or Other. The categories for ethnicity used in this study were Hispanic or Latino and non-Hispanic or Latino. Information was obtained through electronic medical records and self-reports by the patient. The options for educational attainment included 8^{th} grade or less, 9^{th}-11^{th} grade, high school graduate, some college, community college/technical, bachelor's degree, master's degree, doctoral degree, and missing/unreported. The options for marital status included single, married, separated or divorced, widowed, lives with partner, and

missing/unreported. Information was obtained through electronic medical records and self-reports by the patient.

2.2.2. Cancer Type

The cancer type was defined as the primary tumor site of the patient. Validated by our EPIC screening and medical record, these data regarding the specific cancer type was used in our analysis. Cancer types included breast, prostate, endometrial, multiple myeloma, ovarian, and head and neck

2.2.3. Clinical trial knowledge, attitudes, and beliefs assessment

Study participants were asked about their knowledge, attitudes, and beliefs about clinical trials using the 18-item Clinical Trial Knowledge, Attitudes, and Beliefs Assessment. Participants responded to statements such as "The information gained from clinical trials may help a friend or family member", "I think all patients who are eligible should be asked to take part in clinical trials", "I would only take part in a clinical trial if I thought that my own health would benefit". The entire assessment can be in found in Appendix E. The survey has been shown to have a Cronbach alpha of 0.661. Responses were originally developed on a five-point Likert scale that ranged from 1(strongly agree) to 5 (strongly disagree). The assessment was reverse coded to have higher scores reflect having more knowledge and more positive attitudes and beliefs about clinical trials. After the reverse scoring, additive scale score ranges were could range from 49 to 70, and high scores indicate higher knowledge and more positive attitudes and beliefs about clinical trials.

We decided to include this questionnaire in our study because research indicates that cancer patients who are offered or enrolled may have low levels of knowledge about clinical trials (Cox, 2000) or misperceptions about how they function (Curbow, Fogarty, McDonnell,

Chill, & Scott, 2004; Itoh et al., 1997). In general, research has shown knowledge deficits (Curbow, Fogarty, McDonnell, Chill, & Scott, 2004; Ellis & Butow, 1998). Cox (2000) conducted a series of four interviews with 55 patients with advanced cancer who were offered participation in Phase I or Phase II trials. Results indicated that only 16% of the patients could explain the purpose of the clinical trial they were offered. It has been shown that patients often turned down participation if the information about the clinical trial was harder to understand (Curbow, Fogarty, McDonnell, Chill, & Scott, 2004; Lovegrove, Rumsey, Harcourt, & Cawthorn, 2000). Moreover, with increasing numbers of studies on research ethics and a need to improve the recruitment of research subjects, the ability to measure attitudes toward biomedical research has become important (Rubright, Cary, Karlawish, & Kim, 2011).

2.2.4. Decision Control Preferences

Decisional control is often used in the decision science literature to describe patients' ability to play an active role in making decisions about their treatment (Adams & Drake, 2006; Ghane, Huynh, Andrews, Legg, Tabuenca, & Sweeny, 2014). It refers to one's specific role in a treatment decision process rather than a broad approach to health care (Edwards & Elwyn, 206). Patients' decision control preferences for decision partner involvement were measured using the Control Preferences Scale (CPS). The original scale has been used and validated in several studies to assess the degree of control patients prefer over medical decisions with their doctors (Degner & Sloan, 1992).

The question in the original scale was "How do you prefer to make medical decisions with your doctors? The response options from the original scale compared to the response options in the modified scale are described below.

Table 1. Response Options for the Control Preferences Scale

Response Option	Original Scale	Modified Scale
1	I make all medical decisions on my own	I prefer to make the final decision about which treatment I chose
2	I make the final decision myself only after considering my doctor's opinion	I prefer to make the final decision about which treatment I will receive after seriously considering the opinion of my family/friends
3	My doctors and I share decision making equally	I prefer that my family/friends and I share responsibility for deciding which treatment I will receive
4	My doctors make the final decision for me only after considering my opinion	I prefer that my family/friends make the final decision about which treatment I will receive, after seriously considering my opinion
5	My doctors make all medical decisions for me	I prefer to leave all decisions regarding which treatment I will receive to my family/friends

(Degner & Sloan, 1992; Chiu, Feuz, McMahan, Miao, & Sudore, 2016)

There is also a subcomponent of the modified Control Preferences Scale, Part B, that evaluates patients' preferences regarding whether their (1) doctor's input weighs most heavily in decision-making; (2) My family/friends' input weighs most heavily; or (3) My doctor's input and my family/friends' input are equally important. To maintain a sufficient number of cases for statistical analysis per category, we grouped answer options in Part A into two categories that included high decision control preference and deferred decision style. Response 1 was coded to represent high decision control preference (high DCP). Responses 2, 3, 4, and 5 were grouped to reflect a deferred decision style for statistical analyses.

2.2.5. Cancer clinical trial participation.

The primary outcome measure for the study was clinical trial participation among the adult cancer patient-participants. Clinical trial participation was determined through medical record review and self-report from the participants in this study. There were three different responses for this variable, including (1) yes, (2) no, (3) not offered/delayed offer.

2.3 Data Analysis

Descriptive statistics were compared and used to summarize the sample and instrument characteristics. Prior to the main analysis, exploratory analysis was completed to examine the status of missing data as random or systematic and outliers. Missing data were primarily associated with financial information, such as income and employment, as well as level of educational attainment and these missing data were not included in analysis. We performed mean imputation and pair-wise deletion to address missing data related to clinical trial knowledge, attitudes, and beliefs since many of the missing data were related to four participants randomly not answering one item on the 18-item scale. Data generated were reviewed and analyzed using the Chi Square tests or Fisher's exact test as appropriate to examine associations between variables. In addition to assessing associations with decision control preferences for a subset of 26 participants who completed the Control Preferences Scale, we also assessed how patients' knowledge, attitudes, and beliefs about clinical trials differed by gender using t-tests and one-way ANOVA. Due to the small number of patients offered a clinical trial at the time of our analysis, we were not able to perform logistic regression to examine predictors of the clinical trial participation. Instead, we conducted exploratory analyses, including linear regression, to examine predictors of clinical trial knowledge, attitudes, and beliefs. A p-value ≤ 0.05 was considered statistically significant. Statistical analyses were performed with SPSS statistical software.

3. Results

Bivariate analyses were conducted to assess relationships between patient characteristics, decision control preferences, knowledge, attitudes, and beliefs about clinical trials, and clinical trial participation. Given the small percentage of decision partner data obtained (n=12), we were unable to include these data in our statistical analyses.

3.1 Patient demographics, clinical status, decision control preferences, and composite score of clinical trial knowledge, attitudes, and beliefs

Of the 82 participants, 51.2% (n=42) were male and the mean age +/- standard deviation (SD) was 60.55 +/- 12.017 years. Most individuals (32.9%, n=27) were between the ages of 51-60 years old. Of the participants, 73.2% (n=60) were married. Comparison of clinical data indicated that nearly one third (32.9%, n=27) of the participants were diagnosed with prostate cancer, followed by 30.5% (n=25) diagnosed with breast cancer, 19.5% (n=16) diagnosed with multiple myeloma, 12.2% (n=10) diagnosed with head and neck cancer, and the remaining 4.9% (n=4) diagnosed with either ovarian cancer or endometrial cancer. The sample included 53.7% (n=44) White, 36.6% (n=30) Black or African American, 7.3% (n=6) Asian or Asian American, and 2.4% (n=2) identified as Other. Additional demographic characteristics of the total participants are described below. This sample was also highly educated with 61% (n=50) reporting at least some college education among those who completed questionnaire information about their highest level of education completed. Less than 27% (n=7) of the participants who completed the Control Preferences Scale reported a preferred for a high level of decision control, with the remaining 73% (n=19) preferring a deferred decision style.

Table 2. Descriptive Statistics: Demographic Characteristics of the Study Participants (N=82)

	Cancer Patient Sample n (%)
Age, M (SD)	60.55 years (12.02)
30-40	3 (3.7%)
41-50	12 (14.6%)
51-60	27 (32.9%)
61-70	23 (28.0%)
>70	17 (20.7%)
Gender	
Male	42 (51.2%)
Female	40 (48.8%)
Race	
White	44 (53.7%)
African American/Black	30 (36.6%)
Asian/Asian American	6 7.3%)
Other	2 (2.4%)
Ethnicity	
Non-Hispanic	81 (98.8%)
Hispanic	1 (1.2%)
Cancer Type	
Prostate	27 (32.9%)
Breast	25 (30.5%)
Multiple Myeloma	16 (19.5%)
Head and Neck	10 (12.2%)
Other (Endometrial, Ovarian)	4 (4.9%)
Marital Status of Patient	
Married	60 (73.2%)
Single	13 (15.9%)
Divorced/Separated	6 (7.3%)
Widowed	3 (3.7%)
Highest Level of Education Completed	
9^{th} – 11^{th} Grade	5 (6.1%)
High School Graduate	10 (12.2%)
Some College	11 (13.4%)
Community College/Technical	1 (1.2%)
Bachelor's Degree	19 (23.2%)
Master's Degree	11 (13.4%)
Doctoral Degree	8 (9.8%)
Missing/Refuse to Answer	17 (20.7%)
Clinical Trial Knowledge, Attitudes, and Beliefs (Score can range 18-90)	
Mean Score (SD)	64.49 (8.9)
Min Score (Lowest Reported)	49
Max Score (Highest Reported)	86
Range	37
Missing/Incomplete	2
Decision Control Preferences (n=26)	
1) I prefer to make the final decision about which treatment I chose	7 (26.9%)
	10 (38.5%)

2) I prefer to make the final decision about which treatment I will receive after seriously considering the opinion of my family/friends 3) I prefer that my family/friends and I share responsibility for deciding which treatment I will receive 4) I prefer that my family/friends make the final decision about which treatment I will receive, after seriously considering my opinion 5) I prefer to leave all decisions regarding which treatment I will receive to my family/friends	8 (30.8%) 1 (3.8%) 0 (0%)

3.2 Bivariate Analyses of Total Sample

For the total sample (n=82), it was concluded that there was no statistically significant associations with clinical trial participation (yes, no, not offered/delayed offer) among race (p=0.999), ethnicity (p=0.999), gender (p=0.404), age (p=0.154), marital status (p=0.403), education (p=0.550), and CTKAB (p=0.422).

Table 3. Bivariate Analyses: Demographic Characteristics of Patient Participants Grouped by Clinical Trial Participation Decision (N=82)

	Clinical Trial Participation			
Variable n, % (across demographic categories)	Yes (n=13), 15.9%	No (n=8), 9.8%	Not Offered/Delayed Offer (n=61), 74.4%	P Value
Age, M (SD) 30-40 41-50 51-60 61-70 >70	62.9 years (8.7) 0 (0.0%) 1 (8.3%) 4 (14.8%) 5 (21.7%) 3 (17.6%)	62.1 years (11.6) 0 (0.0%) 2 (16.7%) 0 (0.0%) 5 (21.7%) 1 (5.9%)	59.8 years (12.7) 3 (100.0%) 9 (75.0%) 23 (85.2%) 13 (56.5%) 13 (76.5%)	0.154
Gender Male Female	 9(21.4%) 4(10%)	 4(9.5%) 4(10%)	 29 (69.5%) 32 (80%)	0.404
Race White African American/Black Asian/Asian American Other	 7 (15.9%) 6 (20.0%) 0 (0.0%) 0 (0.0%)	 4 (9.1%) 3 (10.0%) 1 (16.7%) 0 (0.0%)	 33 (75.0%) 21 (70.0%) 5 (83.3%) 2 (100%)	0.999
Ethnicity Hispanic Non-Hispanic	 0 (0.0%) 13 (16.0%)	 0 (0.0%) 8 (9.9%)	 1 (100%) 60 (74.1%)	0.999

Marital Status Married Non-Married	 11 (18.3%) 2 (9.1%)	 7 (11.7%) 1 (4.5%)	 42 (70%) 19 (86.4%)	0.403
Education (n=65) High school graduate and below Some college or higher	 1 (6.7%) 9 (18%)	 1 (6.7%) 6 (12%)	 13 (86.7%) 35 (70%)	0.550
Decision Control Preferences (n=26) High DCP Deferred DCP	 0 (0%) 5 (26.3%)	 0 (0%) 2 (10.5)	 7 (100%) 12 (63.2%)	0.240
Knowledge Attitudes and Beliefs about Clinical Trials (n=80)				0.422

*p-value $\leq$ or = 0.05 is statistically significant

3.3 Bivariate Analyses of Participants Offered a Clinical Trial

We conducted bivariate analyses of participants who were actually offered a clinical trial. We had similar results compared to the total sample data. The results show that the association between gender and clinical trial participation was not statistically significant (p=0.646). This was also true for age (p=0.656), education (p=0.999), race (p=0.999), and marital status (0.999) as none of these factors were found to be associated with the decision surrounding clinical trial participation. Though not statistically significant, we found that cancer type was potentially associated with clinical trial participation (p=0.107). Given the small number of participants who responded to the Control Preference Scale (n=26) and the limited number of individuals actually offered a clinical trial, we were unable to examine for any relationship with clinical trial participation. Additionally, marital status was found to have a statistically significant association with decision control preference (p=0.014) with married participants preferring a deferred decision style.

Table 4. Bivariate Analyses: Study Participants Offered a Clinical Trial (N=21)

Clinical Trial Participation Decision (n=21)			
(percentages across row categories)	Yes (total n=13) (n, %)	No (total n=8) (n, %)	P Value
Gender			
Male	9 (69.2%)	4 (30.8%)	0.646
Female	4 (50%)	4 (50%)	
Age			
60 years of age and younger	5 (71.4%)	2 (28.6%)	0.656
Over 60 years of age	8 (57.1%)	6 (42.9%)	
Race			
White	7 (63.6%)	4 (36.4%)	0.999
Non-White	6 (60%)	4 (40%)	
Cancer Type			
Breast	2 (40%)	3 (60%)	0.107
Prostate	6 (75%)	2 (25%)	
Multiple Myeloma	1 (25%)	3 (75%)	
Head and Neck	4 (100%)	0 (0%)	
Other	0 (0%)	0 (0%)	
Marital Status			
Married	11 (61.1%)	7(38.9%)	0.999
Non-Married	2 (66.7%)	1 (33.3%)	
Education			
High school graduate and below	1 (50%)	1 (50%)	0.999
Some college or higher	9 (60%)	6 (40%)	
Knowledge, Attitudes, and Beliefs about Clinical Trials (n=20)			0.373
Decision Control Preference (n=26)			
	High level of decision control (total n=7) (n, %)	Deferred decision style (total n=19) (n, %)	P Value
Gender			
Male	5 (35.7%)	9 (64.3%)	0.391
Female	2 (16.7%)	10 (83.3%)	
Age			
60 years of age and younger	4 (26.7%)	11 (73.3%)	0.999
Over 60 years of age	3 (27.3%)	8 (72.7%)	
Race			
White	3 (23.1%)	10 (76.9%)	0.999
Non-White	4 (30.8%)	9 (69.2%)	
Cancer Type			
Breast	2 (33.3%)	4 (66.7%)	0.999
Prostate	2 (28.6%)	5 (71.4%)	

Multiple Myeloma	2 (28.6%)	5 (71.4%)	
Head and Neck	1 (25%)	3 (75%)	
Other	0 (0%)	2 (100%)	
Marital Status			
Married	2 (11.1%)	16 (88.9%)	0.014
Non-Married	5 (62.5%)	3 (37.5%)	
Education (n=19)			
High school graduate and below	3 (75%)	1 (25%)	0.061
Some college or higher	2 (18.8%)	13 (81.3%)	

*p-value ≤ or = 0.05 is statistically significant

3.4 Exploratory Analysis

Exploratory analyses, including t-tests and linear regression with predictor variables of knowledge, beliefs, and attitudes about clinical trials were conducted. There were no statistically significant differences in knowledge, attitudes, and beliefs about clinical trial by decision control preference groups (p=0.880). We found that race, gender, and education were strong predictors of CTKAB. White participants tended to have a higher mean score for knowledge attitudes, and beliefs about clinical trials (67.28, n=43), than non-white participants (61.24, n=37). Patients with some college education also tended to have higher scores (67.47, n=49) related to knowledge, attitudes, and beliefs about clinical trials compared to those with high school graduate and below (57.73, n=15). Women tended to have higher knowledge, and more positive attitudes and beliefs about clinical trials than men by 4 points on average (p=0.022), even after controlling for education level (p=0.000) and race (p=0.055). Also, white participants tended to have a higher mean score for knowledge, attitudes, and beliefs about clinical trials (mean score of 67.28), than non-white participants (mean score of 61.24), with differences at the edge of significance after controlling for gender and education (p=0.055). Those with some college education tended to have higher scores related to knowledge, attitudes, and beliefs about clinical

trials (p=0.000) by 8 points on average compared to those with a high school degree and below after controlling for race and gender.

Table 5. Exploratory Analyses – CTKAB as Outcome Variable

	B (SE)	P-Value
Race Non-White (Ref group) vs White	3.850 (2.274)	0.055
Gender Female (Ref group) vs. Male	-4.373 (1.854)	0.022
Education High school and below (Ref group) vs. Some college or higher	8.414 (2.262)	0.000

Table 6 also describes the demographic characteristics for the decision partners, including gender, age, race, ethnicity, and relationship to patient.

Table 6. Demographic Characteristics of Decision Partners

Study ID	Gender	Age	Race	Ethnicity	Relationship to Patient
058DP1	Female	55	White	Non-Hispanic	Wife
060DP1	Female	69	Asian/Asian-American	Non-Hispanic	Wife
061DP1	Male	69	White	Non-Hispanic	Husband
063DP1	Female	32	African-American/Black	Non-Hispanic	Grand-daughter
066DP1	Male	68	White	Non-Hispanic	Husband
071DP1	Female	47	White	Non-Hispanic	Husband
072DP1	Male	52	African-American/Black	Non-Hispanic	Friend

076DP1	Male	43	Asian/Asian-American	Non-Hispanic	Husband
076DP2	Female	35	Asian/Asian-American	Non-Hispanic	Friend
078DP1	Male	49	White	Non-Hispanic	Husband
081DP1	Female	55	African-American/Black	Non-Hispanic	Daughter
081DP2	Female	68	African-American/Black	Non-Hispanic	Cousin

4. Discussion and Conclusion

4.1 Discussion

Research on decision control preferences has repeatedly shown that a shared approach to control decision making in healthcare is preferred by the largest group of patients (Schuler et al., 2017). Our results were similar, with the majority of patient-participants (83%) reporting a more deferred decision style. This emphasizes the notion of assessing and addressing patient's decisional control preferences related to involving decision partners in their clinical trial decision-making process. Patients can be supported if they wish to have a friend, family member, neighbor, significant other, or other self-identified individual serve as decision partner.

Furthermore, cancer patients' beliefs and attitudes related to clinical trials and research have been shown to be important personal factors association with clinical trial participation (Bell & Balneaves, 2015). In an integrative review by Bell & Balneaves (2015), it was reported that many studies (36%) found patients' positive beliefs about the benefits of clinical trials were associated with their decision to participate in cancer research, and these beliefs included a desire to help others, perceived personal benefit, and hope for a cure (Bell & Balneaves, 2015; Lara, Higdon, Lim, Kwan, Tanaka, Lau, Wun, Welborn, Meyers, Christensen, O'Donnell, Richman, Scudder, Tuscano, Gandara, & Lam, 2001; Agrawal, Grady, Fairclough, Meropol, Maynard, &

Emanuel, 2006; Avis, Smith, Link, Hortobagyi, Rivera, 2006; Cantania, De Pas, Goldhirsch, Radice, Adamoli, Medici, Verri, Marenghi, de Braud, & Nole, 2008; Catt, Langridge, Fallowfield, Talbot, & Jenkins, 2011; Davison, So, Goldenberg, Berkowitz, & Gleave, 2007; Truong, Weeks, Cook, & Joffe, 2011; Wang, Tsai, Chen, & Tsay, 2011). Due to the limitations in clinical trials being offered to study patients, we were underpowered to detect any statistical significance in associations between knowledge, attitudes, and beliefs about clinical trials and clinical trial participation. In the larger sample of participants that included those who were not offered or received a delayed offer, we found an association (p=0.126) with knowledge, attitudes, and beliefs about clinical trials, compared to those who were actually offered (p=0.566). Given this difference in p-values, future work is needed to further explore potential provider bias and whether or not patients were not offered due to physicians' perceptions and assumptions about a patient's knowledge, attitudes, and beliefs or for clinical ineligibility.

We found no differences in mean age among all three groups: those who were offered and said yes, those who were offered and said no, and those who were not offered or received a delayed offer. We also recognize that 17 participants refused to answer or did not complete survey information regarding education level. Data about education attainment is critical to understand decision making and preferences for decision partner involvement. Results from exploratory linear regression tests and t-tests found that women tended to have higher knowledge, and more positive attitudes and beliefs about clinical trials than men by 4 points on average (p=0.022), even after controlling for education level (p=0.000) and race (p=0.055). There were no statistically significant differences in knowledge, attitudes, and beliefs about clinical trial by decision control preference groups (p=0.880). Also, white participants tended to have a higher mean score for knowledge, attitudes, and beliefs about clinical trials (mean score

of 67.28), than non-white participants (mean score of 61.24), with differences at the edge of significance after controlling for gender and education (p=0.055). Those with some college education tended to have higher scores related to knowledge, attitudes, and beliefs about clinical trials (p=0.000) by 8 points on average compared to those with a high school degree and below after controlling for race and gender. This finding enforces the need to assess health literacy levels and target efforts appropriately to ensure that minority populations have adequate information regarding the importance of clinical trials, as well as improving positive perceptions about research in communities.

4.2. Strengths and Limitations

We recognize that these analyses had several limitations. First, it is important acknowledge that the sample and measures used for this study were limited to those included in the parent study. This limited our ability to incorporate other measures and add more participants into the study design. Second, this study included a relatively limited sample. Statistical power was limited, so possible associations between decision control preferences, gender, race, ethnicity, age, cancer type, marital status, clinical trial participation, and knowledge, attitudes, beliefs about clinical trials, and further clinical characteristics may have been missed and will require drawing on larger sample sizes for future studies to assess for statistically significance. Third, due to the design of the parent study, we were restricted in recruiting patients who were residents of the catchment area of Maryland rather than also targeting patients who lived outside the state. We were also limited to selected cancer types. Findings may be different for patients who lived in other geographic regions and with other cancer types. Fourth, our study was restricted to participants who spoke and understood English. In spite of the racial and ethnic diversity of the region, patients who were non-English speaking

were excluded from the study. However, within the Sidney Kimmel Comprehensive Cancer Center, this does not represent a large group of patients being excluded as our largest minority population is African American. Therefore, we can draw limited conclusions regarding their decision-making about clinical trial participation. Due to the small amount of data about decision partners, we were not able to examine statistical associations with patient data. Future studies should obtain these data for decision partner to be able to draw fuller conclusions. Fifth, the respondents of the questionnaires consisted of individuals who were willing to take part in the study, potentially creating bias. The study may have drawn respondents who were particularly interested in cancer, clinical trials, or decision control preferences for decision partner involvement in treatment decision-making. Furthermore, future studies should measure patients' intent or willingness to participate in a clinical trial needs and compare those findings with actual clinical trial offer and actual participation. Sixth, there may be potential social desirability bias in how participants completed the questionnaire about knowledge, attitudes, and beliefs about clinical trials. More psychometric testing is needed to accurately and objectively measure understanding and perceptions about clinical trials. Seventh, there may have been bias in how potential participants were screened using the algorithm due to random error. Lastly, this was a highly educated sample, with 61% of those reported to have at least some college education. This could create potential bias in their preferences to involve decision partners in decision making and what they knew about clinical trials.

Despite the limitations, there were several strengths of this study. First, the study sample was racial and ethnically diverse, and reflected the ethnic make-up of the region where the study was conducted. Second, the sample included a nearly equal number of males and females with a wide range of cancer types among adult cancer patients. Third, we were able to obtain

information about barriers to clinical trial decision making and participation, given the high number of participants who were ineligible (75%, n=61). These data helped to provide insight about a clinical trial enrollment and future recruitment and retention needs of patients.

4.3 Future Research

There is a need for more diverse study samples and research staff members to reflect the populations they serve. Decision control preferences as well as knowledge, attitudes, and beliefs about clinical trials may be different across racial/ethnic groups. Large studies are also needed to further stratify by decision control preferences, cancer type and stage, and education levels to examine associations with clinical trial decisions.

4.4 Practice Implications

Healthcare providers will need to undergo dedicated training to learn how to incorporate information about patients' decision control preferences into care and decision making. There is also a need for accurate electronic medical record reporting of both disease stage and clinical trial discussions that occur between clinicians and patients to better identify gaps in screening and eligibility. Furthermore, rather than simply asking the patient "do you understand?", patients should be asked to explain their understanding of the proposed clinical trial, and offered time to think about the information and to discuss this with others (Jefford et al., 2010). Cancer patients make difficult treatment decisions, so it is important to assess their decision control preferences at the time of diagnosis and then intermittently throughout the course of illness. Additionally, a question prompt list (QPL) would be a valuable aid for patients facing difficult treatment decisions. QPLs consist of a written sample of questions that have demonstrated a significant promise in aiding doctor-patient communication and promote patient question asking (Brown, Shuk, Leighl, Butow, Ostroff, Edgerson, & Tattersall, 2011).

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Conflict of interest

The authors have no conflicts of interest to disclose.

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CHAPTER V: Manuscript Three: Qualitative Study Results

This chapter, focused on the qualitative study results, is the last of three manuscript papers that comprises this dissertation. It is the authors' intent to submit this article to the Qualitative Health Research Journal. There is a required format for this journal submission, which includes a title page, methods, ethics, results, and discussion. The references should be written in APA format on a separate page and include pertinent references only. The Qualitative Health Research Journal does not have a word or page count limit. Journal instructions encourage this submitted manuscript to be as concise as possible, preferably less than 30 pages including references. The journal also require that the figures, charts, and tables are in the main text rather than at the end of the document. The abstract is unstructured, written in 150 words, should be the first page of the main manuscript, and it should be on its own page.

Title: "Choose Your Own Adventure": Perspectives from Adult Cancer Patients and Their Decision Partners Regarding Clinical Trial Decision-Making and Involving Others

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Abstract

This exploratory descriptive study explores the process of decision making about clinical trial participation among persons with high levels of decision control preferences and those with a deferred decision style. We interviewed 12 adult outpatient cancer patients and 12 decision partners to gain their experiences and perspectives about clinical trial decision-making and learn about the role of decision partners in decision-making. Patients were recruited from a sample of individuals who were already enrolled in a parent study and decision partners were selected by patients. We used the process of inductive analysis to conceptualize codes into themes. Most of the patients (83%) reported a deferred decision style and 58% of the total sample was non-White and 54% female. Themes included: 1) Having the freedom to choose; 2) Getting the most insight about clinical trials; 3) Relationship building...Trusting *someone* in the process; and 4) Realizing readiness and context.

Keywords:

Decision partner, family, decision-making, relational autonomy, clinical trial participation, adults, qualitative

Background

Clinical trials are critical to advances in the understanding and treatment of cancer (Joffe, Cook, Cleary, Clark, & Weeks). Clinical trials are necessary for the improvement of patient care as they help to confirm the efficacy and safety of novel cancer treatments and in so doing, contribute to a solid evidence base on which practitioners and patients can make informed treatment decisions (Bell & Balneaves, 2015). Unlike in other diseases (Christofides, Dobson, Solomon, Waters, & O'Doherty, 2016), individuals with cancer heavily depend on clinical trials as a way to fight against their disease with the hope of survival and cure. Other cancer patients decide to participate for altruistic reasons to help future cancer patients (Truong, Weeks, Cook, & Joffe, 2011). However, despite its role in advances, clinical trials among adult cancer patients is currently as low as 3-5% (Wang, Tsai, Chen, & Tsay, 2011; Brown, Cadet, Houlihan, Thomson, Pratt, Sullivan, & Siminoff, 2013). Lack of participation compromises the success of clinical trials and squanders an opportunity for improving patient outcomes (Bell & Balneaves, 2015). Clinical trial participation may involve unknown risks and benefits, and the decision-making process to enroll in a study may be overwhelming and confusing for patients. Clinical trials are often presented near the time of a new diagnosis when patients are particularly emotionally, physically, and mentally vulnerable (Thorne et al., 2013; Rutten, Arora, Bakos, Aziz, & Rowland, 2005), taking more physical and mental energy than patients can afford (Butow, Maclean, Dunn, Tattersall, & Boyer, 1997). Additionally, discussing complex treatment decisions, such as clinical trial participation, may result in increased patient distress and reduced ability to focus on and process critical information (Chen, Rossignac-Milon, & Higgins, 2018; Laryionava, Pfeil, Dietrich, Reiter-Theil, Hiddemann, & Winkler, 2018).

In general, the decision of selecting a specific cancer treatment can be difficult and anxiety-producing and the hardship of decision making is even greater when the options include clinical trials. Moreover, illness is a biological and social process. A cancer diagnosis and subsequent treatment decisions affect a person's entire social network, from family, to friends, to peers and colleagues. In an effort to bolster coping support and to receive assistance with treatment decision making, patients with cancer often to loved ones as sources of support when considering information about their diagnosis and treatment options including clinical trials. Although, families and friends are recognized as engaging in cancer care and treatment, there is a knowledge gap in understanding the way in which those relationships influence the patient's decision-making specifically about clinical trial participation.

Research that explores the clinical trial decision-making tends to focus on the decision-making process of only the patient, neglecting the role that decision partners may have in the process. For this article, we have defined decision partners as family or friends who are engaged in decision-making about clinical trial participation with the patient and serve as trusted sources of support (Wenzel et al., 2015). Rather than assuming that patients make decisions in isolation, it is imperative to recognize the importance of social circumstances and significant relationships on individuals' self-determination that may impact decision-making (Bell & Balneaves, 2015). The appreciation of patients' preferences regarding participation in decision making is crucial in order to be able to individualize disclosure of information and patient involvement (Schuler, Schildmann, Trautmann, Hentschel, Hornemann, Rentsch, Ehninger, & Schmitt, 2017). This importance particularly applies to oncology, not only because the identification of patients' preferences for information and control is important to avoid the often-occurring conflicts between patients' expectations and physicians' decision-making practices (Schuler et al., 2017).

In marked contrast to the relatively well-developed body of quantitative literature on factors related to clinical trial accrual, qualitative research exploring the clinical trial decision-making processes of cancer patients has been minimal, with only 15 studies having been conducted to date (Bell & Balneaves, 2015). The degree to which family members influenced patients' choices for the patients' own good (versus the family's good), how they were involved in the decision-making process, and patients' preferences with regard to the involvement of their family in clinical trial decisions, however, remained largely unexplored (Bell & Balneaves, 2015). We also know that physicians often make assumptions about patients' preferences for decisional control that may be inaccurate (Ghane, Huynh, Andrews, Legg, Tabuenca, & Sweeny, 2014).

Purpose

Therefore, an exploratory descriptive design was used to elicit first-hand descriptions of patient and decision partner experiences and perspectives about clinical trial decision-making. We explored how adult outpatient cancer patients approach clinical trial decision-making based on their varying levels of decisional control preferences for decision partner involvement. We included patients who reported high levels of decisional control preferences (DCP) and those persons with a deferred decision style as well as included decision partners, as selected by the patients, to gain their experiences and perspectives about being involved in clinical trial decision-making.

Methods

Setting and Recruitment

Study participants were recruited from a large comprehensive cancer center in the mid-Atlantic region of the United States. Participants in this study included both patients and decision

partners who the patients self-reported. We selected patients who decided to participate in a cancer clinical trial, not participate in a cancer clinical trial, as well as those who were not offered a clinical trial at the initial clinic visit when baseline data were being collected for the parent study but who were screened to have an available clinical trial. Patients that we recruited for this study were already consented and enrolled into a parent study, the EMPaCT Patient Navigation Study, which focused on evaluating the effectiveness of a patient navigation program to increase recruitment and retention into cancer clinical trials.

Since the patients were already consented and enrolled into the parent study, the inclusion criteria were similar to the inclusion criteria of the parent study. Inclusion criteria included that the patients had completed the Control Preference Scale, had a primary tumor cancer diagnosis (breast, prostate, multiple myeloma, ovarian, endometrial, head and neck), were screened to have an available therapeutic cancer clinical trial as identified through medical record review, had residency in the state of Maryland, aged 18 years or older, and were able to read, write and understand English. The inclusion criteria for decision partners included being 18 years or older, and who were able to read, write and understand English, and identified as a decision partner by the patient. Each participant received up to $30 and a parking voucher as needed for their participation. We approached or made a phone call to 19 patients about participating in an interview about the decision-making process regarding clinical trial participation and their perceptions about involving decision partners in that process. Two patients were deceased at the time when the interviews were conducted, four patients never returned our phone calls for participation, two patients were approached in clinic after being introduced to the study over the phone but never responded back to follow up phone calls to set up an interview time, and a

phone call was made to one patient who deferred to a later time and never returned follow-up calls.

Methodology

We interviewed patients from a variety of reported scores on the modified version of the Control Preference Scale that examined decision control preferences for decision partner involvement in decision making. We aimed to apply maximal variation sampling to allow for a fuller understanding of how patients, from a range of decision control preferences, make decisions and how they prefer to involve decision partners and others in decision making. The Control Preference Scale (CPS) was developed by Degner and colleagues (Degner, Sloan, Venkatesh, 1997). Participants were selected for interviews based on whether the patients completed the CPS. On this scale, patients could pick one statement out of five that best describes their preferred involvement in medical decision making. The ranges of options are described below in Table 1.

Table 1. Grouped Categories for Patients' Decision Control Preferences

High DCP	Deferred DCP
"I prefer to make the final decision about which treatment I will receive"	"I prefer to make the final decision about my treatment after seriously considering the opinion of my family/friends" "I prefer that my family/friends and I share responsibility for deciding which treatment is best for me" "I prefer that my family/friends make the final decision about which treatment I will receive, but seriously consider my opinion" I prefer to leave all decisions regarding my treatment to my family/friends"

*Grouped decision control preferences are denoted as the *patient's* decision control preference beside quotes from both patients and their decision partners

There was also a subcomponent of the Control Preferences Scale that evaluated patients' preferences regarding whether their (1) doctor's input weighs most heavily in decision-making; (2) My family/friends' input weighs most heavily; or (3) My doctor's input and my family/friends' input are equally important.

A semi-structured interview guide was developed by the study team through formative exploration of the available literature, clinical experiences and input, and informal peer and expert review. Data collection occurred over a four-month period from November 2017 to March 2018. Audio-recorded telephone, video, or face-to-face interviews were conducted by a single interviewer, the first author, who had clinical and research experiences working with adult cancer patients and families as a certified oncology nurse. Semi-structured interviews were chosen as the most appropriate method for our study, as the alternatives, structured or unstructured interviews, would offer little opportunity for free expression (Newell, 1994) or risk losing control of the focus of the conversation respectively (Yan & Wildemuth, 2009). We scheduled interview dates, times, and location based on participant preferences and the availability of private interview space within the clinic. Participants had the option to choose to participate in individual interviews, dyadic interviews, or separate interviews with their decision partner present if the patient had identified a decision partner. The interviewing options were provided to maximize the setting in which the participants would feel most comfortable. The interviews were, on average, approximately 25 minutes in length, ranging from 16 minutes to 1 hour. Table 2 presents examples of selected interview questions we used.

Table 2. Selected Interview Questions

Patient Interview Questions	**Decision Partner Interview Questions**
Topic: Patients' preferences to involve decision partners in health-related decisions	
Related to your cancer care, how do you like to include people in health-related decisions?	In what ways do you think families or decision partners should and can be involved in decision making?
Topic: Knowledge and Perceptions about Clinical Trials	
What are your ideas about participating in research? When you hear the term *clinical trial*, what comes to mind? Were you offered to participate in a clinical trial? If so, please tell me some of the reasons why you decided to participate or not participate?	When you hear the term *clinical trial*, what comes to mind? What do you think about if your loved one were to be invited to participate in a clinical trial? What do you think [patient pseudonym] knows about clinical trials?
Topic: Timing to Discuss Clinical Trials	
When do you think is an ideal time to discuss clinical trials?	When do you think is an ideal time to discuss clinical trials?
Topic: Decision partner role in clinical trial decisions	
Who is important to discuss a clinical trial decision with? What role does [decision partner pseudonym] play in helping you reach a decision about participating in a clinical trial?	Could you tell me about how you are involved in the decision related to whether or not [patient pseudonym] participates in a clinical trial?
Topic: Recommendations to improve clinical trial decision-making.	
What would make the process of deciding whether or not to take part in a clinical trial easier or better?	What would make the process of deciding whether or not to take part in a clinical trial easier or better?

Ethics

Ethical approval for this study was obtained from the Johns Hopkins Medicine Institutional Review Board (JHM IRB) (NA_00072282). Prior to the start of each interview, oral consent was obtained with the participants via face-to-face at outpatient clinic visits, via

telephone, or video, depending on which method was most convenient for the participant. Consenting, data recording, and interview transcription procedures were conducted in accordance with JHM IRB policies. To provide privacy and confidentiality, all participants were advised that their responses would remain anonymous and that all individual identifiers would be removed from the data. Names in this manuscript have been replaced with a pseudonym. Only those details interpreted as necessary to understand the findings have been reported.

Data Analysis

The final sample size was determined by the number of interviews required to reach informational redundancy, and data saturation was determined after conferring with data coders and consulting qualitative research mentors. We audio recorded and professionally transcribed verbatim the interviews, checked for accuracy in the transcription, de-identified prior to analysis, and then uploaded the transcripts into Nvivo Version 11 to organize data and facilitate analysis. We analyzed the data using hermeneutic phenomenological analysis, which involves the reflection on the data, explication of themes, and discernment of patterns to fully understand the essence of the lived experience for participants, with a focus on their shared experience and perspectives (Bynum & Varpio, 2018). Two first and second author were involved in the line-by-line review of each interview and performed the first phase of analysis independently. Transcripts were first read several times independently by the first and second authors to allow for general impressions for the content to develop into categories and preliminary codes. Pre-coding, also known as first-level coding, was the first step of the analytical process that included circling, highlighting, underlining, or bolding, rich or significant quotes or passages that were particularly notable (Saldana, 2016). The data were then individually coded and analyzed by the first and second author who participated in weekly analysis meetings. We analyzed a subsample

of the coded segments throughout the coding process to verify the coding scheme and inter-rater agreement.

Next, the process of inductive analysis continued as categories emerged from coded segments, a process known as second-level coding (Saldana, 2016). We then compared second-level codes of data to conceptualize the codes into themes that describe the meaning of experiences related to the process of decision-making about clinical trial participation. Once a codebook was developed, all codes were reviewed and collapsed into categories and themes through an iterative process of classifying, comparing, grouping, refining and data reduction (Sandelowski, 2000; Bakitas, Dionne-Odom, Jackson, Frost, Bishop, & Li, 2016). Themes were defined as clusters of linked categories that convey similar meaning. The primary author returned often to the audio recordings and transcripts through a recursive process to verify interpretations and applications of the codes and themes. Once preliminary findings were decided on between the first and second author, the findings were shared with the remaining authors, who were content and methods experts and peers. Any discrepancies between the first and second author were also brought to this study team and a final decision was made after further discussion that included a re-evaluation and comparison of the coded data. After receiving input from the study team, findings were refined, as presented below.

We enhanced study trustworthiness, including credibility, dependability, and transferability (Graneheim & Lundman, 2004) via four strategies. First, we maintained an audit trail of study activities, including field notes from each interview. Methodological and analytical memos were also used for documenting decisions related to refining and defining codes, patterns, or categories as a way to document communications from the research team. This allowed the authors to recognize and separate his or her own thought processes from those of the

participants. Second, the primary interviewer had expertise in both clinical practice and research of pediatric and adult cancer patients, and the peer and expert reviewers had experienced with qualitative analyses focusing on chronic illnesses and family research. Third, at each stage, coding was completed by at least two researchers, and discrepancies were discussed and clarified. Fourth, dependability was obtained by having the same researcher (first author) conduct all interviews over a relatively short period of time (4 months). Overall, data analysis was an iterative process to support thematic analysis (Braun & Clark, 2006) that involved discussions of the analytic decisions with members of the research team until a consensus was reached.

Results

Demographics and Participant Characteristics

Patient interviews were undertaken with 24 adult cancer patients (n=12) and decision partners (n=12) who consented to participate in the study. We calculated descriptive statistics with SPSS Statistical Software Premium GradPack 25 for Windows. Total participants were mostly female (54%, n=24) and mostly white (42%, n=10), followed by 38% (n=9) African American/Black. The average age and standard deviation (SD) of an adult cancer patient who participated in the interviews was 59.8 years (10.4), with a range of 42 to 74 years. The average age and SD of a decision partner was 53.4 years (13.1), with a range of 32 to 69 years. Most (58%, n=7) of the decision partners were spouses of the patients, 17% (n=2) were either children or grandchildren, 17% (n=2) were either friends or colleagues, and the remaining decision partner (8%, n=1) was identified as a cousin. Most of the adult cancer patients had a primary cancer diagnosis of breast cancer (25%, n=3) or prostate cancer (25%, n=3), followed by individuals diagnosed with multiple myeloma (25%, n=3), head and neck cancer (17%, n=2), and

ovarian cancer (8%, n=1). Of the twelve patients, 50% (n=6) had been offered a cancer clinical trial or received a delayed offer pending prerequisite medical information. Furthermore, over half of the patients (58%, n=7) reported to prefer making final decisions about treatment after seriously considering the opinion of family or friends, rather than equally sharing in the decision-making process with family or friends (25%, n=3) or making the final decision without the input of others (17%, n=2). A full description of the characteristics of the participants can be found in Table 3.

Table 3. Demographic Characteristics of the Qualitative Study Participants (N=24)

Decision Partner and Patient Demographic Characteristics		
Demographic Characteristics	Patient (n=12) n, %	Decision Partner (n=12) n, %
Age (years)		
M (SD)	59.8 (10.4)	53.4 (13.1)
Range (Min-Max)	42-74	32-69
Gender		
Female	7 (58%)	6 (50%)
Male	5 (42%)	6 (50%)
Race		
White	5 (42%)	5 (42%)
African American/Black	5 (42%)	4 (33%)
Asian/Asian American	2 (16%)	3 (25%)
Ethnicity		
Non-Hispanic	12 (100%)	12 (100%)
Hispanic	0 (0%)	0 (0%)
Clinical Characteristics of the Patient		
Cancer Type of Patient		
Breast	3 (25%)	
Prostate	3 (25%)	
Multiple Myeloma	3 (25%)	
Head and Neck	2 (17%)	
Ovarian	1 (8%)	
Time Since Cancer Diagnosis		
< 1 year ago	5 (42%)	
1-2 years ago	3 (25%)	
>2-3 years ago	4 (33%)	
Social and Decisional Characteristics of the Patient		
Number of Patients Who Reported Having a Decision Partner		

Yes	10 (83%)
No	2 (17%)
Marital Status of Patient	
Married	10 (83%)
Single	1 (8%)
Widowed	1 (8%)
Decision Partner's Relationship to Patient	
Spouse	7 (58%)
Child or grandchild	2 (17%)
Friend or colleague	2 (17%)
Cousin	1 (8%)
Decisional Control Preferences	
"I prefer to make the final decision about my treatment after seriously considering the opinion of my family/friends." (Deferred)	7 (58%)
"I prefer that my family/friends and I share responsibility for deciding which treatment is best for me." (Deferred)	3 (25%)
"I prefer to make the final decision about which treatment I will receive." (High DCP)	2 (17%)

Themes

Combined interview analysis categorized the participant data into five themes that were related to the decision-making process about clinical trial participation.

Theme 1: Having the freedom to choose

Theme 2: Getting the most insight about clinical trials

Theme 3: Building relationships...Trusting *someone* in the process

Theme 4: Realizing readiness and context

Theme 1: Having the Freedom to Choose

The first theme that emerged from the data was "*having the freedom to choose*". When discussing clinical trial decision making, both patients and decision partners discussed the importance of "*having the freedom to* choose" as having more than one treatment option from

which to choose, having access to care that could include clinical trials, demonstrating decision-making self-efficacy, maintaining a sense of autonomy, and that having the freedom to choose was based on being comfortable in gathering and processing information about clinical trials from either the patients' or decision partners' standpoint.

Having multiple options. A core component of decision-making is identifying that there is more than one option from which to choose among others. In the interviews, patients and decision partners expressed their recognition that a clinical trial was only one treatment option from which they could choose, even if the other options included standard therapy, a risky procedure, or waiting to treat. One decision partner noted that her mother, who was enrolled in a clinical trial, was given an option to undergo a risky procedure that would alter her life substantially or the clinical trial. She explained that: *"Yeah, the fact that we'd even consider that as an option-- you would have to have tried everything possible before you could even consider that…so I don't really call that an option, but that's what she was offered."* (081DP1, 55 yo, female, patient with deferred DCP).

Access to care. Another aspect of *"having the freedom to choose"* was about access to care, specifically regarding access to clinical trials. All participants lived in the same state, an area that has numerous health care systems and options for care. Some lived near prominent health care systems that conducted many clinical trials while others lived farther away and shared their care with the local community hospital with more limited treatment or trial options. Regardless of where they lived, participants had access to various health care systems, and many of them deliberately chose the cancer center where this study was conducted because of its reputation, expansive treatment options including clinical trials, and renowned doctors. In the interviews, participants recognized that there were many places to receive care, but there was a

sense of "not wanting to settle" for suboptimal care: *"I felt that I wanted to come where I could get the best treatment."* (057P, 65 yo, male, high DCP). They explained that if the clinical trial was the best hope for a cure and best treatment option for them, they would be open to participating. Therefore, *having the freedom to choose* involved having access to care that may include clinical trial was regarded as important in the decision-making process, regardless of their decision control preferences, because some participants deliberately sought out research-intensive health care systems that would likely offer clinical trials. One patient, a male with a deferred decision style who was enrolled in a clinical trial, said that "*we always feel very thankful to have [the cancer center] as a 10-minute ride from our house to have some of the best doctors and some of the best people working research on these diseases so readily available to me.*" (058P, 55 yo, male, deferred DCP). For another clinical trial-enrolled patient who lived more than an hour away from the cancer center, her decision partner shared that since the patient could not get to the appointments herself, the patient's two decision partners "*work together as a team...it took all three of us because she can't get to herself to the appointments*." (081DP1, 55 yo, female, patient with deferred DCP). The other decision partner explained that "*because you needed a commitment…everybody needed to be on board.*" (081DP2, 68 yo, female, patient with deferred DCP). In this specific context, the patient and decision partners knew that having access to care and to the clinical trial influenced their perceptions about having the freedom to choose about clinical trial participation.

Demonstrating decision-making self-efficacy. Within the theme of *"having the freedom to choose"* emerged an additional subtheme related to self-efficacy in decision-making or the confidence to make decisions. Decision-making self-efficacy became evident as a trait that influenced participants' ability to make clinical trial-related decisions. Patients with a deferred

decision style expressed trust and assurance in their decision partners' confidence and ability to assist in decision-making about clinical trials, even if the patients themselves lacked confidence or seemed unsure of their ability to make that decision. Similarly, one patient with a high DCP, stated that they were more focused on making the final decision about clinical trial participation after gathering information by reading articles, pamphlets, and searching on the Internet, without necessarily asking for the input of others.

> *"I do have research skills and I had research different providers-- I researched their backgrounds, their educational history. I actually consider myself to be quite savvy as it pertains to that."* (057P, 65 yo, male, high DCP)

Among participants, having confidence in their ability to make this difficult decision was important because there were many options and different people had different opinions about what was best. More specifically, making decisions about clinical trial participation can be a process of uncertainty because there are many unknowns. Therefore, exhibiting traits of self-efficacy in decision-making, for either decision partners or patients, is necessary as one decides about clinical trial participation because there are high-stakes consequences involved.

For one patient (058P, 55 yo, male, deferred DCP) who was diagnosed with cancer a second time, his wife was his decision partner. She shared her approach in helping her husband decide about clinical trial participation, exhibiting confidence, even in the midst of uncertainty.

> *"We looked at what they'd already seen, what had already happened with those two drugs or that, whatever-- we did a lot of research to see if we thought that would work for him. It was like a here-we-go-again type thing. We knew…Well, we weren't sure…so we had to make a decision based on what we knew at that moment."* (058DP1, 54 yo, female, patient with deferred DCP)

Similarly, another decision partner, a husband of a patient with previous history of multiple cancers, asserted confidence in decision-making:

> *"I mean, <chuckles> first of all, it's like choose your own adventure. Right? If you go down this road, what happens? If we go down this road, what happens? What are the odds? The*

> *best way you can present it is to say what are the odds for what the best case scenarios are going forward? You know, in choose your own adventure, you just basically click on the page and say this is where it's going to go, right?"* (076DP1, 43 yo, male, patient with deferred DCP)

Maintaining a sense of autonomy. Decision partners and patients both expressed the importance of having the patient maintain a sense of autonomy in clinical trial decision-making, despite their decision control preferences. Decision partners expressed the idea of respecting patient autonomy in decision making, given the complex nature of the decision. Although her doctor discussed treatment options, one patient noted that "*I went and I went looking... you need to be comfortable and trust your doctor. But you need to ask questions too and you need to go in with your questions ready...we're just curious people and we're not afraid to ask questions."* (061P, 58 yo, female, deferred DCP). Many participants also expressed the importance of *having the freedom to choose* who was involved in decision-making, often limiting to a small network of individuals in the process in order to maintain a sense of autonomy and privacy. Children or extended family were usually made aware of the decision but not necessarily involved in the process. It was described by one patient that: *"Sometimes family can be very helpful, sometimes not so much. Every case is different"* (061P, 58yo, female, deferred DCP). Another patient stated:

> *"Certainly they [family] could disagree with you and then you thought you had the right decision and be afraid to say I'm doing what I want to <laughs>, I feel like that could be a challenge."* (066P, 63 yo, female, deferred DCP).

Comfort in gathering and processing information. The theme *having the freedom to choose* is also about the comfort level of the individuals to be able to gather and process information about clinical trials. From the interviews, it was revealed that if participants did not feel comfortable gathering and processing information about clinical trials, then their ability to

have the freedom to choose was significantly impacted because they were not able to ask questions, unsure of what was being discussed, and could not adequately receive and process the information to make an informed decision. One decision partner described that:

> *"The first thing you do is go into research mode, so try to find out as much information as you can and let people who do what they do and go from there. I think both of us went into the research mode; just find out as much as we could."* (058DP1, 54 yo, female, patient with deferred DCP).

Another participant, a decision partner shared that

> *"I think it depends on-- you do it case-by-case and depending on their health literacy on how much they can digest at a given time."* (076DP2, 35 yo, female, patient with deferred DCP).

Theme 2. Getting the Most Insight about Clinical Trials

Regardless of the reported decision control preferences, in order to make decisions about clinical trial participation, patients and decision partners both discussed the value of getting as much insight as possible about clinical trials. In order to optimize their knowledge about clinical trials, broaden their perspectives, and facilitate clinical trial decision making, participants reported learning from multiple sources, including consulting with different providers, social media and blogs, television, browsing different search engines, reading research articles, in addition to talking with family members, friends, and colleagues who had experience in research or healthcare systems in order to gain different perspectives and as much information as possible about clinical trials. One participant shared that:

> *"I suppose I would probably talk to my oncologist, and I would probably talk to my friends or colleagues who are oncologists, if there was some question or concern I had….it's good to have somebody who has that depth of understanding to be able to, you know, run by issues, and to kind of sort through what seems to be a reasonable path forward."* (078P, 49 yo, female, deferred DCP).

Another patient said:

> *"We would seek out the opinion of more than one professional."* (061DP1, 69 yo, male, patient with deferred DCP).

Moreover, other participants verbalized a desire to be able to talk in-depth to individuals who may have the most insight about clinical trials such as research team members, patients who were enrolled or had participated in the specific clinical trial that they were considering or patients who have participated in clinical trials in the past, patients with a similar diagnosis, and their oncologist or the doctor who was leading the specific clinical trial.

One patient stated:

> *"I know with HIPAA laws, your doctor can't say "Oh, here's two people I'd like you'd to call and they're participating and see what they think." I don't know if that somehow a.. once-a-month support group that met somewhere where, if people had questions, they could come in and discuss type of thing."* (058P, 55 yo, male, deferred DCP)

Another patient said:

> *"I'd definitely like to know if somebody else has done them before, I mean because they are something that I feel like is not as tried and true, I guess I should say. So I'm open to them but I'm still very hesitant because I feel like it's-- unless I know somebody who's been through it and has come out okay <laughs> on the other side, it feels like it's a little riskier. To have people who have been through them before is definitely a good thing. I know it's helpful for me to know somebody who's in my same situation, at least as far as my diagnosis goes, and I think if a clinical trial was to happen to be able to talk to somebody who's maybe been through a similar trial."* (071P, 45 yo, female, deferred DCP)

Individuals with a high DCP reported to not asking many, if at all, questions about clinical trials. Instead, they preferred to gather information on their own by reading about clinical trials, relying on their own perceptions and assumptions, or trusting the recommendation of either their primary care doctor or oncologist. Individuals with a deferred decision style reported that they often dialogue together with their decision partner as well as bring in selected extended family

members and multiple providers' input. Here is one account from a decision partner about how they *get the most insight* during clinical trial decision-making if one was presented to his wife.

> *"We ask a lot of questions. Yeah. We think about it a lot and ask questions and read about it and early on her brother was involved because he was actually involved in the research that came up with the drug that she's using now, with the clinical trial with animals. He was very interested and gave us a lot of information."* (066DP1, 63yo, male, patient with deferred DCP)

Theme 3. Building Relationships…Trusting Someone in the Process

When asked specifically about what comes to mind when they hear the term "clinical trials", participants provided responses including: risky, experimental, unproven, an opportunity to receive new treatments, an avenue to pave the way for others to receive new therapies and to advance scientific knowledge. Since the risks and benefits of clinical trials are often unknown, participants discussed the importance of developing a trusting relationship with someone as they are deciding about clinical trial participation.

Partnership and trust with provider. Even though patients varied in their decision control preferences, all patients as well as many decision partners shared the importance of having a strong relationship with their oncologist or their primary care provider when making decisions about clinical trials.

> "*I love my oncologist. I've been very, very happy with my doctor. But I think the more that the oncologists know, the front line, the better off. They're the ones who typically lead people. They're the ones you need to talk to.*" (061P, 58yo, female, deferred DCP).

> *"I'm in a good relationship with all of them, because I don't know."* (063P, 70 yo, male, deferred DCP).

> "*Any question that I do have, I put it to my oncology physician, my attending, and she's been very helpful.*" (070P, 65 yo, male, deferred DCP).

Network and access to people. Some participants trusted the input of family members who had previously participated in a clinical trial, which helped them in their decision-making

process. For example, one patient said that since her brother went through a clinical trial and is now in remission, then she "*has a lot of faith in a clinical trial.*" (081P, 74 yo, female, deferred DCP). Additionally, for patients with decision partners, they described their relationships with decision partners as invaluable to the decision-making process. Those patients who reported a deferred decision style reported that the role of the decision partner included being an important advisor, supporting the patient's decision-making and autonomy, being available for the patient, offering guidance and reassurance, and serving as a listener ear to discuss different options. Decision partners shared similar comments by describing their role as helping the patient consider the treatment options, weigh out the consequences of being in a clinical trial, and be able to provide an extra set of ears to hear the information that was being delivered by the health care team.

One decision partner shared that:

> *"Oh, everything gets bounced off of me. We both make the decision jointly."* (066DP1, 63yo, male, patient with deferred DCP).

Whether patients had been offered or not offered a clinical trial, those with a deferred decision style acknowledged that it was important to talk about it with their decision partner to some extent. Some patients described decision partners as being a sounding board, meaning that they were someone that patients trusted and wanted to be a part of decision-making with them. One patient talked about the role of her husband:

> *"Even factoring in genetics and everything else, there was still some concern on my part, and he was a good sounding board to have for that, but he's the primary person that I've spoken to about it other than my doctors."* (071P, 45 yo, female, deferred DCP)

This patient's husband shared that:

> *"I think it's important to have someone else to be that sounding board."* (071DP1, 47 yo, male, patient with deferred DCP)

Another patient also used the word "sounding board" to describe the role of her husband, who was her decision partner and had experience in health care:

> *"He also understands a lot about drugs, he's a good sounding board, and it's good to have somebody who has that depth of understanding to be able to, you know, run by issues."* (078P, 49 yo, female, deferred DCP).

It was also important for participants to utilize their social networks and their access to certain people, such as researchers and physicians, in order to facilitate clinical trial decision-making. In the interviews, social networks and access to certain people were often associated with the participants' work or familial networks. One decision partner had a medical background and she described the important role of utilizing her networks when helping her friend in the clinical trial decision-making process:

> "*But I do know that I can ask for help and I-- of course, I can access the health system where it's very collaborative. So, I can always-- I always have colleagues.*" (076DP2, 35 yo, female, patient with deferred DCP).

Building a culture of research and seeking those with an invested interest. Others reported that access to research and clinical staff was important when making a clinical trial decision about clinical trial participation in order to build a culture of research where patients and decision partners can feel supported, have positive experiences with research and clinical trials, and can trust that researchers and providers who are conducting the clinical trials have an invested interest in the patients when asking them to consider clinical trial participation. With regards to building the culture of research, it was important to talk with members of the research team early on during the decision-making process. One decision partner shared that:

> *"Communication at any time in any kind of study will go a long way. Even if you were just scared about something, just to have somebody acknowledge that they heard you is huge."* (058DP, 54 yo, female, patient with deferred DCP).

Another participant shared a similar response:

> *"Just whoever is involved with the trial...and maybe the doctor in charge of it."* (066DP1, 68 yo, male, patient with deferred DCP).

Another patient had a high DCP and did not identify a decision partner. He responded differently when asked about whether it was important to talk with the research team. He replied:

> "*In all candidness no, because my thought is that, if they are the research team, then they have a vested interest in it. I would think that, if I needed medical advice per se, I would get that advice from a primary care physician."* (057P, 65 yo, male, high DCP).

Theme 4. Realizing Readiness and Context

The decision-making process also involved meeting the patient where they are in their current emotional readiness, clinical situation, as well as health literacy and knowledge about clinical trials.

Being emotionally ready. In the interviews, there was a growing consensus that there was no ideal or exact time to introduce clinical trials as a treatment option and it was important for decision partners and providers to meet and support the patient where they are both emotionally and clinically in the decision-making process. One decision partner gave insight about his friend:

> *"She distances herself sometimes she don't hear everything the doctor is saying and sometimes, you know, she could have questions because she distances herself from the situation."* (072DP1, 52 yo, male, patient with high DCP).

Another patient shared that:

> "*I'm not even sure what clinical trials are. I'm not sure…Sometimes my thoughts and stuff is not that so I'm clear and stuff and so a lot of times and sometimes I'm not sure what they're asking me or what's saying."* (072P, 59 yo, female, high DCP).

Unique to the individual. Giving patients time to cope with the diagnosis prior to making a clinical trial decision was discussed most frequently among participants. Many participants explained that the process of clinical trial decision-making can be overwhelming when trying to cope with a cancer diagnosis:

> *"I think at the first diagnosis it might be a little early <laughs>. Kind of get what-- kind of used to what's happening to them. I don't know other than just having the doctor aware that there are some out there that would be beneficial to their patient".* (066P, 63 yo, female, deferred DCP)

Depends on cancer type and disease progression. Some noted that clinical trials should be viewed as a last resort treatment option and that it was important to consider the cancer type and disease progress when deciding about clinical trials.

> *"I think it depends on what kind of cancer you have. It really depends. I think you definitely need to look into it when you've tried the normal things and they're not working anymore."* (061P, 58 yo, female, deferred DCP)

Other participants expressed the benefit of learning about the possibility of a clinical trial early in the diagnosis in order to be adequately prepared to make a decision.

> *"Well, I think that, once a person is diagnosed, I think that it's very important to reach them at a very early stage shortly after being diagnosed*". (057P, 65 yo, male, high DCP)

	Theme 1: Having the freedom to choose	Theme 2: Getting the most insight about clinical trials	Theme 3: Building relationships… trusting *someone* in the process	Theme 4: Realizing readiness and context
Subthemes	Multiple options	Learning from multiple sources	Partnership and trust with provider	Unique to the individual
	Access to care	Talking with people with insight into clinical trials	Network and access to people	Being emotionally ready
	Maintaining sense of autonomy	Talking with people with a research or medical background	Seek those with an invested interest	Depends on cancer type and disease progression
	Demonstrating decision-making self-efficacy		Building a culture of research	
	Comfort in gathering and processing information			

Figure 1. Themes and subthemes from the qualitative interviews.

Discussion

There is an extensive body of literature describing the barriers and facilitators experienced by patients related to clinical trial participation (Bell & Balneaves, 2015). Most clinical trial participation research has focused on enrollment as the primary outcome rather than the process of decision making (Biedrzycki, 2010). Moreover, prior research is limited in its understanding of patients' perspectives of the decision-making processes surrounding clinical trial participation and the sociopolitical context in which these decisions are made (Bell & Balneaves, 2015). In particular, researchers have been slow to adopt a relational autonomy lens when exploring cancer patients' clinical trial decisions despite growing recognition in the bioethics literature of the significance of social networks and sociopolitical influences on patients' autonomy within general health care decision-making processes (Bell & Balneaves, 2015). Guidelines for the ethical conduct of human subjects research even demand that

researchers are aware of the potential for individuals to be unduly influenced by others (Bell & Balneaves, 2015), and such influences could include decision partners. Therefore, our exploration of the process of decision making about clinical trial participation among persons with varying decision control preferences presents an important opportunity to examine patients' decision control preferences and potential influence on clinical trial decision-making.

This study has highlighted the critical role of decision partners for adult cancer patients as they make clinical trial-related decisions, especially given that most of the individuals in our sample reported a deferred decision style (83%). Research on decision control preferences has repeatedly shown that a shared approach to control decision making in healthcare is preferred by the largest group of patients (Schuler et al., 2017). The findings from this study suggest that as patients make clinical trial decisions, it is important to develop and maintain relationships with people they trust, evaluate their unique circumstances, have the freedom to choose and maintaining a sense of autonomy, and acquire as much insight as possible about clinical trials, even among patients with varying decision control preferences. Participants also shared that decision-making self-efficacy is needed in clinical trial decision-making due to its unknown outcomes. This trait could be demonstrated by either the patient or the decision partner. These findings are similar to other qualitative studies, where the level of trust patients had in their doctors' recommendation regarding whether a trial would be an appropriate medical option for them was an important factor that predominantly influenced clinical trial decision making (Brown, Shuk, Leighl, Butow, Ostroff, Edgerson, & Tattersall, 2011). Research has shown that physicians and their relationship with patients are important factors in patients' decisions about clinical trial participation (Bell & Balneaves, 2015).

Of note, half (50%, n=6) of the patients in the study were offered or received a delayed offer for a clinical trial. This suggests that eligibility criteria and other factors remain a major barrier in being able to make decisions about clinical trial participation. Studies have described health care providers as "gatekeepers" to clinical trials and these individuals have a direct influence on the participation rate of their patients (Salman, Nguyen, Lee, & Cooksey-James, 2016), which appears to be similar in our findings. Similar to other studies (Hill, Mogle, Wion, Kolanowski, Fick, Behrens, Muhall, & McDowell, 2017), we found that relationships with the research team also impacts a patient's decision to participate in a clinical trial. Nonetheless, it was important for the participants to gather as much information and insight into clinical trials as possible before making a decision.

The theme, *realizing readiness and context*, was described as an important aspect of the decision-making process. In short, clinical trial offers should include an understanding of the importance of emotional readiness and cancer type of the patient. Research has shown that the decision of selecting a specific cancer treatment is difficult and anxiety-producing, and the hardship is even greater when the options include clinical trials, as experimental treatments have no proven benefits (Wray, Stryker, Winer, Demetri, & Emmons, 2007), and decision made under the pressure of life-threatening disease by cancer patients may limit attention to and comprehension of consent materials (Wray, Stryker, Winder, Demetri, & Emmons, 2007; Huizinga, Sleijfer, van de Wiel, & van der Graaf, 1999).

In the past, patients' attitudes toward living with cancer have been shown to affect whether they can decide to accept or decline participation in cancer phase I clinical trials with or without hesitating or wavering (Kohara & Inoue, 2010). Additionally, patients' attitudes toward clinical trials can also affect their decision. A conservative attitude towards risk-taking can be a

barrier for patients and prevent them from participating in a clinical trial (Lee, Ow, Lie, & Dent, 2016). In line with previous research, many of our participants described clinical trials as risky, unproven, and experimental, which impacted how they make decisions about clinical trial participation.

Furthermore, the patients and decision partners had diverse experiences with cancer, clinical trials, health care systems, and came from different occupational and educational backgrounds. Thus, when clinical trials are offered, it is important to consider the context of that individual patient and communicate in a way that is well understood, allowing patients to make informed choices. Research suggest providing a question prompt list for patients as they have discussions about clinical trials (Brown et al., 2011) and evaluating their level of understanding about research (Joffe, Cook, Cleary, Clark, & Weeks, 2001). These question prompt lists may help level the opportunities that patients have about getting insight and information about clinical trials by first knowing what questions to ask.

Strengths and Limitations

There are some limitations that are inherent to this type of research. First, this study may present potential biases in the data in that those who participated in the interviews were limited to include participants who were already enrolled in the parent study who completed the Control Preferences Scale. Second, it is important to keep in mind that the study participants who consented had a desire or willingness to participate in the interviews, which may potentially lead to biases in the data. Those patients who refused to participate in the qualitative interviews (36%, n=7) may have reported similar or dissimilar views regarding clinical trial decision-making and the role of decision partners. Unfortunately, we were not able to gain further insight into why some people chose not to be interviewed.

Third, there is potential for socially desirability bias, where participants may have answered questions in a manner that will be viewed favorably by others. Fourth, it is important to recognize the demographic characteristics of the participants. We were limited to adult cancer patients living within one state in the southeastern part of the United States with selected types of cancer diagnoses based on the parent study. Furthermore, findings may be different for individuals who lived in other geographic regions and with other types of cancer diagnoses. Fifth, in the interviews, we asked participants to reflect on the sum of their experiences from initial diagnosis to past and current treatment to clinical trial treatment decision making. Since the majority of our patients were diagnosed within the last 2 years (67%), most of our patients and decision partners did not have difficult recalling information. However, when conducting qualitative interviews about past and present experiences, there is possibility of some recall biases in their responses. Sixth, not all interviews were completed in the same manner, so this may have been both a limitation and a strength to elicit experiences and perspectives about clinical trials. Seventh, given the hypothetical nature of this study, some individuals were not offered a clinical trial during the initial clinic visit when baseline data was collected for the parent study, while others were offered a clinical trial. Nonetheless, findings from analyses can be useful in planning targeted outreach and education about clinical trials as well as to potentially improve recruitment approaches for clinical trial participation.

Despite these limitations, this research study has numerous strengths. The dyadic approach of our research enhanced our ability to understand the role of decision partners in the clinical trial decision-making process and how their role may affect clinical trial participation. The perspectives of the decision partners help to contextualize and elaborate on the characteristics of the adult cancer patient that may affect decisions related to clinical trial

participation, such as sociodemographic factors including educational level, age, gender, and race. Moreover, dyadic interviews allow for an interaction between participants in the interview and observations of how the comments of one participant draw forth responses from the other (Morgan, Ataie, Carder, & Hoffman, 2013). This kind of interaction facilitated the exchange of stories, which were particularly valuable as qualitative data (Morgan, Ataie, Carder, & Hoffman, 2013). In addition, the qualitative interviews explored a broad range of topics including preferences to involve others in decision-making and perceptions about the word *clinical trials*. Furthermore, the sample included a nearly equal number of males and females for both patients and decision partners, a fairly broad range of cancer types among patients, and a racially diverse sample of individuals that reflected the makeup of the geographic region of the state where the study was conducted. Larger studies that include other diverse racial and ethnic groups will be useful to fully explore clinical trial decision-making across individuals who vary by decisional control preferences and determine their different needs for decision partner involvement.

Conclusions

Future research about clinical trial decision-making and the role of decision partners is essential to the development of clinical trial recruitment and retention, especially considering the social context in which patients reside in while making these decisions. The previous experiences that decision partners, family members, and friends have with regards to clinical trials may influence how patients make decisions about participation in important ways. Future research is required to further examine the provider-patient relationship and how clinical or research interactions also involve decision partners. Additionally, whether or not patients enroll in a clinical trial, it is important to understand and support their decision-making processes and support patients and decision partners as needed. Future work should focus on patients' decision

control preferences for decision partner involvement being evaluated early at the time of diagnosis and then re-assessed intermittently throughout the course of illness.

CHAPTER V: Qualitative Study References

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CHAPTER VI: Conclusions and Implications

Summary and Future Research

There is a growing body of literature related to cancer treatment decision-making, globally, as well as specific factors that impact cancer clinical trial participation. This dissertation study is among the first to examine patients' decision control preferences for decision partner involvement and the role of decision partners in clinical trial decision-making for adult cancer patients using quantitative and qualitative data sources in order to obtain multiple perspectives and a fuller understanding of their role.

In the quantitative arm of the dissertation study, we found that 73% (n=19) reported a deferred decision style. In the qualitative arm, most patients (83%, n=10) identified at least one decision partner, but some patients did not (17%, n=2). Follow up studies should investigate reasons why some patients do not identify a decision partner and focus on developing ways to support their decision making. Research is also needed to understand why patients choose certain friends or family as their decision partners, and whether decision partner choice alters based on the type of decision or health context. Another area of future research should examine whether involvement of decision partners is correlated with more positive patient health outcomes and improved patients' satisfaction with care, especially with our findings indicating that patients most often prefer a deferred decision style with decision partner involvement.

Moreover, studies are needed to design and test psychometrically sound instruments to capture the latent variables that are associated with decision-making, knowledge, attitudes, and beliefs about clinical trial participation, and accurately measure health literacy about clinical trials. In the larger sample of participants who were not offered or received a delayed offer, we found a pattern of potential association (p=0.126) with knowledge, attitudes, and beliefs about

clinical trials, compared to those who were actually offered (p=0.566). Given this difference in p-values, future work is needed to potential provider bias and whether or not patients were not offered due to physicians' perceptions and assumptions about a patient's knowledge, attitudes, and beliefs or for clinical ineligibility. Particularly, with the increasing numbers of studies in research ethics and a need to improve recruitment of research subjects, the ability to measure attitudes towards biomedical research has become important (Rubright, Cary, Karlawish, & Kim, 2011). With smaller sample of participants who were actually offered a clinical trial (in spite of all participants being screened as having at least one available clinical trial) limited power to detect statistically significant associations among variables, but we did recognize trends and patterns among certain sociodemographic variables such as gender, cancer type, and knowledge, attitudes, and beliefs about clinical trials, and clinical trial participation. Future work should also focus on creating and implementing conceptual frameworks that take into account patients' decisional control preferences and show how these preferences fit into decision-making, plans of care, and patient outcomes.

Research is also needed to develop and evaluate multi-faceted and multi-leveled interventions that aim to integrate decision partners more fully into the clinical trial decision-making process with health care teams. Our findings indicated that relationships were critically important in decision making and decision partners are often described as people that patients trust. We also learned from many interviews that patients also trust providers' input with regards to clinical trial decision making. When decision partners, providers, and patients work together in clinical trial decision making, there is an opportunity for multiple perspectives to be shared that impact decision making. Furthermore, decision partners have the potential to help bridge communication gaps between patients and clinicians and contribute to a greater understanding

about a patient's personal, social, and community contexts as patients navigate within a health care system. In the interviews, the majority of the decision partners shared their experiences with research and clinical trials, working in health care, caring for a sick family member, had a background in public health, or held leadership positions in their career that led to them being strong patient advocates and resourceful with gathering information.

Future studies may also focus on better understanding the impact that a cancer patient's clinical trial participation has on the decision partner, the family, and within the workplace setting if the cancer patient is still working full-time while enrolled in a clinical trial. With the incorporation of stated-preference methods, researchers will be able to understand valuation and prioritization of key stakeholders in decision making, including patients, decision partners, employers, providers, insurance companies, and family members.

Conclusions and Implications

It is important to recognize that there are certain populations that continue to be vulnerable across many clinical contexts, including clinical trial decision making. Disparities continue to exist in cancer health outcomes. Furthermore, the lack of diversity in clinical trials can greatly compromise the outcomes of the trials since cancer varies greatly among gender, races, and cultures (Salman, Nguyen, Lee, & Cooksey-James, 2016), and this lack of diversity in clinical trials slows our progress in reducing cancer health disparities. Furthermore, the accrual and retention rates remain significantly lower in the adult cancer patients compared to pediatrics. Our study sample had a median age of 60.5 years. Within this sample, we learned that 75% (n=61) of the individuals were either not offered or received a delayed offer regarding a clinical trial. This supports existing literature that older adults remain underrepresented in cancer clinical trials because of frequent comorbidities and related trial ineligibility (Mancini, Jansen, Julian-

Reynier, Bechlian, Vey, & Chabbannon, 2014). Physicians are less likely to discuss this option with them (Mancini, Jansen, Julian-Reynier, Bechlian, Vey, & Chabbannon, 2014; Javid, Unger, Gralow, 2012), and older adults have been found to prefer a passive decision making role with their physicians (Lechner, Herzog, Boehlen, Maatouk, Saum, Brenner, & Wild, 2016). Therefore, it is important for decision partners to be present to help advocate for such opportunities, especially if these decision partners bring knowledge about research and health care. Also, patients with lower health literacy levels are likely to prefer a passive role in decision-making (Mancini et al., 2014), making decision partners even more pivotal in the decision-making process.

Furthermore, participants in this study were receiving care from an outpatient setting, which is an underserved population with regards to understanding their supportive care needs within the health care system and having access to resources if they were otherwise inpatient to help them make informed decisions. Research have suggested that one in two outpatient cancer patients have not used any of the existing and available supportive and palliative care services since their diagnosis (Kumar, Casarett, Corcoran, Desai, Li, Chen, Langer, & Mao, 2012), and those who utilize these services were more likely to have a higher level of education (Adler & Newman, 2002; Kumar et al., 2016). For these outpatient cancer patients, as was in our sample, it is critically important to have decision partners to help in decision making, considering that they often live close to the patients or in frequent communication with them.

Geographic proximity is also another important in clinical trial decision making. Patients who do not live close to the clinic or near a health care facility that conducts clinical trials could be greatly disadvantaged. Most cancer clinical trials are only available at academic and cancer centers, and the accessibility of these trials is very limited for most of the ethnic minority cancer

patients who live in and receive treatment in their ethnic community (Salman, Nguyen, Lee, & Cooksey-James, 2016; Lin, Finlay, Tu, & Gany, 2005). For patients who do not drive long distances, decision partners may be essential in influencing patients' decisions about clinical trial participation if they are willing to help with getting patients to appointments and help the patient meet other clinical trial commitments.

As we learned from this study, many patients with greater knowledge and more positive attitudes and beliefs about clinical trials either had prior experience with clinical trials or knew someone in their social network who had had a positive experience participating in clinical trials. Therefore, it is critical to learn more about who these decision partners are who are involved in decision making and understand their backgrounds and familiarity with clinical trials as they are influential in aiding in impeding clinical trial participation.

Finally, we need to look beyond oncology populations and investigate the role of decision partners in other illnesses, diseases, and types of decisions. The highly complex, dynamic and interrelated character of many family decisions suggests that decision-making processes could be studied more effectively across decisions, rather than in relation to any given decision independently (Douglas, 1983).

CHAPTER VI: Conclusions and Implications References

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LIST OF APPENDICES

Appendix A: Letter Confirmation from JHU Medicine IRB regarding approval for dissertation study regarding the addition of the modified Control Preferences Scale questionnaire.

JOHNS HOPKINS
MEDICINE

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street, Reed Hall, Suite B-130
Baltimore, Maryland 21205-1911
410-955-3008
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Date: August 1, 2016

CHANGE IN RESEARCH APPROVAL

Review Type:	Expedited
Principal Investigator:	Dina Lansey
Number:	NA_00072282 / CIR00020037
Title:	Individual Characteristics and Research Decisions in Cancer Care at Johns Hopkins
Committee Chair:	Susan Bassett
IRB Committee:	IRB-X

Date of approval: July 29, 2016

Date of Expiration: May 17, 2017

The JHM IRB approved the above-referenced Change In Research.

Approval to include;
1) Added Hua-Ling Tsai to the study team;
2) Section 20 (Supplemental Study Documents), 2 revised questionnaires and added 8 new questionnaires.

IRB review included the following:

45 CFR 46.116: A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

Study Team Members:
This approval includes study team member changes. See below for a list of approved study team members.

There is an institutional policy which governs the participation of post-doctoral fellows in research. Please see: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/post_doc.html. You are responsible for ensuring that any post-doctoral fellows on the study team meet all criteria for participation pursuant to this policy.

Morgan Patullo, Mohammad Khan, Ahmed Hassoon, Gary Grossfeld, Xiujuan Peng, Jennifer Wenzel, Meikue Pawla, Anita Miller Hart, Pritish John, Jing Ye, Sarah Sagorsky, Kunhwa Kim, Eden Stotsky-Himelfarb, Amar Srivastava, Janet Heussner, Norma Kanarek, Akshay Gupta, Melissa Kurtz, Jeffrey Hardesty, Sandra West, Tamryn Gray, Hua-Ling Tsai, Rosa Sebree, Lisa Sherden, Stacie Jeter, Olive Mbah, Hyunseok Kang

Appendix B: Letter Confirmation from JHU Medicine IRB regarding approval for dissertation study regarding the oral consent documents for the qualitative interview and decision partner data collection.

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Institutional Review Boards

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Date: September 11, 2017

CHANGE IN RESEARCH APPROVAL

Review Type:	Expedited
Principal Investigator:	Dina Lansey
Number:	NA_00072282 / CIR00030246
Title:	Individual Characteristics and Research Decisions in Cancer Care at Johns Hopkins
Committee Chair:	Susan Bassett
IRB Committee:	IRB-X

Date of approval: September 11, 2017

Date of Expiration: May 1, 2018

The JHM IRB approved the above-referenced Change In Research.

Approval includes a revised eForm A dated 08/16/2017 submitted in S6, Q2-3, the addition of Bayview as a Hopkins site submitted in S10, Q1, an increased sample size in S11, checking 'yes' to healthy volunteers in S12, Q5, checking 'Hopkins/Affiliates outpatients' in S12, Q6, checking 'Individuals who learn about the study through advertisements or peer/network recruiting' in S13, Q1, revised recruitment information in S13, Q2, checking 'letters' in S13, Q6, the addition of one recruitment document in S13, Q7, revised consent waiver in S14, revised written consent in S15, Q3, the addition of IROC in S15, Q10-15, the addition of oral consent in S16, two new oral consent documents submitted in S16, Q2, two new supplemental study document submitted in S20, Q2, and revised SKCCC CRO submitted in S34, Q2.

Please note that the IRB made additional changes to your consent form(s) prior to approval. You may view the revised consent form(s) uploaded in the Written Consent section of the eIRB application. Click on View to the left of the document name, then click History and open the document with the name starting with 'irb_.' If you do not agree with these changes, submit a change in research application with a revised consent form(s). If you submit a change in research application, use the IRB's clean copy of the consent form(s) to make additional revisions. To maintain an accurate history in eIRB, do not delete the consent form(s). If you are making additional changes, use the Update button to upload your revised copy(ies).

IRB review included the following:

Use of an oral consent process.

45 CFR 46.117(c)(2)/21 CFR 56.109(c)(1): The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

Study Team Members:
Kunhwa Kim, Lisa Sherden, Alesandra Seal, Rosa Sebree, Stacie Jeter, Sandra West, Jennifer Wenzel, Tamryn Gray, Melissa Kurtz, Pritish John, Akshay Gupta, Eden Stotsky-Himelfarb, Jing Ye, Sarah Sagorsky, Meikue Pawla, Jeremy Todd, Norma Kanarek, Xiujuan Peng, Gary Grossfeld, Morgan Patullo, Olive Mbah, Janet Heussner, Jeffrey Hardesty, Mohammad Khan, Hyunseok Kang, Ahmed Hassoon, Amar Srivastava, Hua-Ling Tsai, Anita Miller Hart

Appendix C: Interview Guide

EMPACT Enhancing Minority Participation in Clinical Trials

Participant Interview Guide
(Patient and Decision Partner)

Date: _____ **Participant ID or Pseudonym**: _____

Time (Start/End): _____ **Interviewer**: _____

INTRODUCTION:

Thank you for agreeing to participate. I am interviewing you to learn about your experience in making health-related decisions and in working with EMPaCT patient navigators.

This interview will last no more than one hour. By the end of this interview, I would like to have an overall picture of your experience. Do you have any questions before we begin?

Part 1 – Interview Questions for Patient Participant

BACKGROUND QUESTIONS:

I would like to ask you a few questions before we get started to learn a little bit more about you.

1. **Why don't we talk about the time you were diagnosed with cancer?**
   PROBE: How were you feeling? How were you processing it?

2. **Related to your cancer care, how do you like to include people (family, friends, doctor, nurses) in health-related decisions?**

3. **One of the reasons that I contacted you for an interview is to understand how you made a decision about whether or not to participate in research. In general, what are your ideas about participating in research?**
   PROBES:
   - **a.** What had you heard about research studies and clinical trials before one was offered to you as a treatment option?
   - **b.** When you hear the term *clinical trial*, what comes to mind?
   - **c.** What do you think about when you are invited to participate in a clinical trial?

4. **Were you offered other clinical trials before this one, and did you decide to participate?**
   - **a.** *IF NO: clarify answer*, e.g. not offered other clinical trials? Or no to participation?
   - **b.** *IF YES:* Please tell me some of the reasons why you decided not to participate in those other trials.

INTERVIEW QUESTIONS:

Please keep in mind that whenever I say "clinical trial", I am referring to the clinical trial in which [PATIENT NAVIGATOR NAME] worked with you.

Motivation

5. What motivated you to participate [or not participate] in this clinical trial?

PROBES:

- **a.** Was the clinical trial your only treatment option?
- **b.** Who did you discuss clinical trial participation with?
  - **i.** Your doctor? Your nurse? What did he/she tell you?
  - **ii.** Family and/or friends who serve as a decision partner? What did they tell you?
- **c.** What role did *[DECISION PARTNER NAME]* play in helping you reach a decision about participating in the clinical trial?
- **d.** What role did *[PATIENT NAVIGATOR NAME]* play in helping you make the decision to participate in the clinical trial?
- **e.** What are the benefits of including your decision partner in clinical trial decisions?
- **f.** What are the challenges in including your decision partner in clinical trial decisions?

6. Did you have any concerns about taking part in THIS clinical trial?

- **a.** *IF YES:* What were the main concerns you had about taking part in this clinical trial?

PROBE: What did you anticipate when you were thinking about enrolling in this study?

PROBE: For example, related to clinical trial requirements, your family, how the research is done, the drug itself, other treatment related concerns

- **b.** In the case of your concerns about *[FILL IN CONCERN MENTIONED ABOVE]*, were these concerns addressed? By whom?

PROBE: How did you overcome these concerns? During recruitment/screening process? After enrollment?

PROBE: How did others help you to overcome these concerns?

i. Family/friends?
ii. Doctors?
iii. Nurses?
iv. *If doctors or nurses not mentioned above:* Did *you* discuss your concerns with your doctor or nurse?

Experience with Patient Navigator

7. How did you first come in contact with your patient navigator, [*PATIENT NAVIGATOR NAME*]?

PROBE: Had your doctor or nurse told you that a patient navigator would be contacting you?

- **a.** Think back to the time when *[PATIENT NAVIGATOR NAME] first* called you. Do you remember what you thought or how you felt about her contacting you?

PROBE: Was the call welcomed, or did you think the call was intrusive? *In what way was it [welcomed/ intrusive]?*

- **a.** What were your thoughts about being contacted by someone you did not know who wanted to discuss barriers you might have to cancer treatment or participation in a clinical trial?
- **b.** What questions did *[PATIENT NAVIGATOR NAME]* discuss during that first call?
- **c.** Was there anything that you did not discuss with her that you needed to?

8. **Please tell me about your experience working with the patient navigator [*PATIENT NAVIGATOR NAME*].**
   PROBES:
   - **a.** How would you describe the interactions and your overall relationship with the navigator? OR
   - **b.** Please describe your view of the navigator's role in working with you.
   - **c.** How did the navigator assist you in understanding what was required of you as a participant in the trial as you were making a decision whether or not to participate?
   - **d.** What did the navigator help you with?
   - **e.** To you, what was the most important part of working with *[PATIENT NAVIGATOR NAME]*?
   - **f.** Was there anything about *[PATIENT NAVIGATOR NAME]* that made you feel confident that she could help you?
   - **g.** What things were you less confident about *[PATIENT NAVIGATOR NAME]* helping you with?
   - **h.** Was there anything about *[PATIENT NAVIGATOR NAME]* that made you feel uncomfortable?
   - **i.** Did *[PATIENT NAVIGATOR NAME]* encourage you to discuss your concerns with your doctor or nurse, give you reminder calls, meet you in the clinic etc?
   - **j.** Did *[PATIENT NAVIGATOR NAME]* give you medical advice for example, recommending over the counter drugs?
     - **i.** *IF YES:* What was the advice?

9. **What was your impression about how *[PATIENT NAVIGATOR NAME]* worked with the rest of the clinic team, for example with the clinic staff, the nurses, or the doctors?**
   - **a.** To you, did it seem like she was part of that team? Why or why not?

   PROBE: How is your communication with the patient navigator different than your communication with the other research staff such as nurses or doctors?

Part 2 – Interview Questions for Decision Partner

1. **What is it like being invited with the [*PATIENT'S PSEUDONYM*] as they make health-related decisions?**

2. **Could you tell me about how you were involved in the decision related to whether or not [*PATIENT'S PSEUDONYM*] participated in research studies or clinical trials?**

3. **What has helped you as you participate in the decision-making process?**

4. **What are some of the challenges in participating in the decision-making process?**

Part 3 – Interview Questions for Patient and Decision Partner

Lessons learned

1. **What would make the process of deciding whether or not to take part in a clinical trial easier or better?**

2. **What things can we do to make the patient navigator program better for this clinical trial?**
   PROBES:
   - **b.** What were you satisfied with?
   - **c.** How the navigator got in touch with you the first time (and afterwards)?
   - **d.** Information that the navigator shared and discussed with you?
   - **e.** The frequency/mode/duration of interaction?

3. **For those considering participation in this clinical trial, would you recommend that other participants work with a patient navigator? A decision partner? Why or why not?**

4. **Any final thoughts about the patient navigator program or your experience with your navigator *[PATIENT NAVIGATOR NAME]* that you would like to share with us?**

Appendix D: Survey Instruments Table

Patient Data – Race, Ethnicity, Age, Gender, Education, Cancer Type, Marital Status, Clinical Trial Offer, Clinical Trial Participation					
Theoretical Concept	**- Instrument**	**Measurement**	**# of Items**	**Score**	**Cronbach's α**
Decision Control Preference*	Control Preferences Scale (Baseline)	*Control Preferences Scale (CPS)* Slight modifications were made to this scale to assess participation preference for treatment decisions with providers. The CPS consists of five cards that each portrays a different role in treatment decision-making using a statement. These roles range from the individual making the treatment decisions, through the individual making the decisions jointly with the decision partner and/or physicians, to the decision partner and/or physician making the decisions	2	One of five possible scores (from independence to shared decision making to decision-making reliant on decision partner)	0.76-0.92 (Original version—CPS has been modified for the proposed study)
Clinical Trial Knowledge	Clinical Trial Knowledge Assessment	*Clinical Trial Knowledge Assessment* To measure understanding of key concepts in clinical trials	18	Parent study-developed	0.661
Decision Partner Data - Race, Ethnicity, Age, and Gender (oral questionnaire)					

Appendix E. Clinical Trial Knowledge, Beliefs, and Attitudes Assessment

Clinical Trial Knowledge, Beliefs, and Attitudes Assessment

People participate in clinical trials for a variety of reasons. Rate your agreement/disagreement with each of the following statements concerning participation in a clinical research trial:

Rating: Strongly agree, Agree, Neutral, Disagree, Strongly Disagree

	Strongly Agree	**Agree**	**Neutral**	**Disagree**	**Strongly Disagree**
1. The information gained from clinical trials may help a friend or family member diagnosed with my same illness in the future.	◯	◯	◯	◯	◯
2. Clinical trials often offer the best treatment available.	◯	◯	◯	◯	◯
3. Most of the current treatments for cancer are based on evidence from previous clinical trials.	◯	◯	◯	◯	◯
4. I would not participate in a clinical trial due to potential side effects.	◯	◯	◯	◯	◯
5. All possible measures to protect my safety and privacy are taken in a Johns Hopkins Hospital-sponsored clinical trial.	◯	◯	◯	◯	◯
6. If most patients refused to take part in clinical trials, important developments in medicine would be seriously delayed.	◯	◯	◯	◯	◯
7. It is important for me to be compensated financially for my participation in a clinical trial.	◯	◯	◯	◯	◯
8. Without results from clinical trials, doctors would be less able to select the best treatment for my age, race, and ethnicity.	◯	◯	◯	◯	◯

9. I think all patients who are eligible should be asked to take part in clinical trials.	◯	◯	◯	◯	◯
10. I am worried that taking part in a clinical trial will inconvenience me.	◯	◯	◯	◯	◯
11. I would only take part in a clinical trial if I thought that my own health would benefit.	◯	◯	◯	◯	◯
12. I think I would find being in a clinical trial frightening.	◯	◯	◯	◯	◯
13. I trust my doctor and would participate in a clinical trial if she/he recommended I do so.	◯	◯	◯	◯	◯
14. Participating in clinical trials may provide new, and often expensive, treatment to patients at reduced costs.	◯	◯	◯	◯	◯
15. I know someone who has participated in a clinical trial.	◯	◯	◯	◯	◯
16. I have participated in a clinical trial in the past.	◯	◯	◯	◯	◯
17. I believe clinical research trials are important.	◯	◯	◯	◯	◯
18. The results of a clinical trial that I participated in may help others in the future with my same diagnosis.	◯	◯	◯	◯	◯

Appendix F. Modified Control Preferences Scale

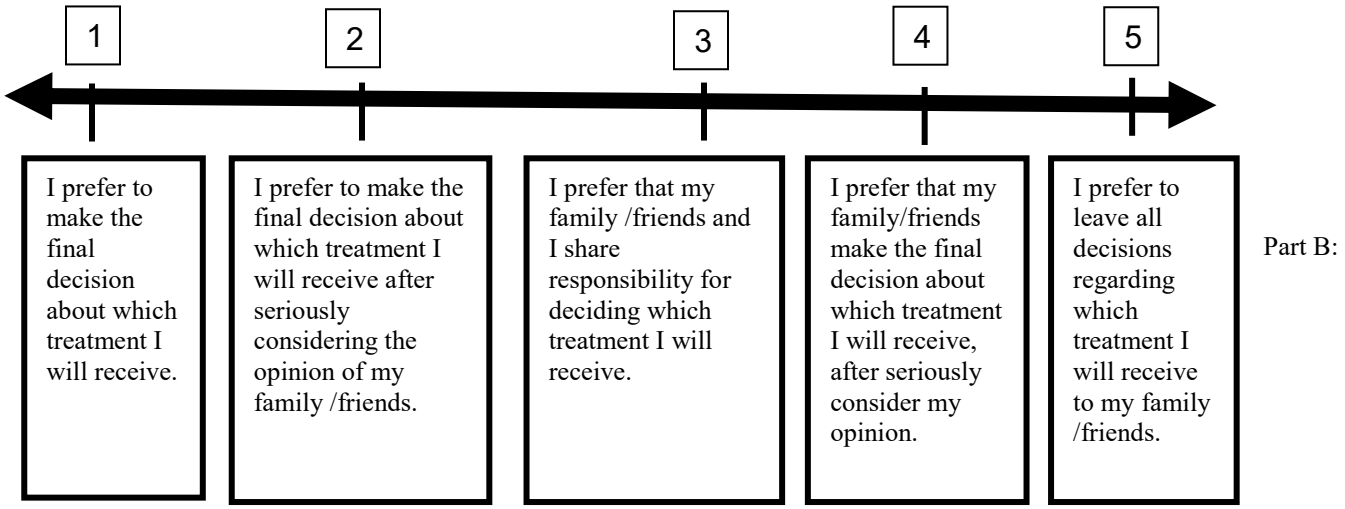
EMPACT Enhancing Minority Participation in Clinical Trials

Date: _____	**Version 1 Pre:** _____
Participant ID: _____	**Version 2 Post:** _____

Control Preferences Scale

The role you want other people to play in your health care treatment decisions is important. This questionnaire looks at the level of control in which you want family members and/or friends to assume when decisions are being made about your cancer-related treatment. Tell us how you would like treatment decisions to be made by circling one text box.

Part A:



Part B:

Physician vs. Family and Friends

In making decisions about your health care now, how do you weigh the input of your doctor and the input of your loved ones? **Circle one.**

1 = My doctor's input weighs most heavily.

2 = My family/friends' input weighs most heavily.

3 = My doctor's input and my family/friends' input are about equally important.

Appendix G. Inclusion/Exclusion Criteria for Quantitative Study

Quantitative Study Inclusion/Exclusion Criteria (Same as Parent Study)

Inclusion Criteria	Exclusion Criteria
• Must be over 18 years • Patient has a primary solid tumor cancer diagnosis [initial focus: Breast, Colon, Lung, Pancreas, Prostate, Multiple Myeloma, or Head and Neck] • Patient must have an available therapeutic clinical trial, identified through pre-screening/medical record review • Resident of Maryland • Able to read and write in English*	• Do not have an available therapeutic clinical trial through pre-screening/medical record review • Not a resident of Maryland

*added to dissertation study inclusion criteria

Appendix H. Inclusion/Exclusion Criteria for Qualitative Study

Qualitative Study Inclusion/Exclusion Criteria

Adult Cancer Patient	Decision Partner
• Must be 18 years or older • Patient has a primary solid tumor cancer diagnosis [initial focus: Breast, Colon, Lung, Pancreas, Prostate, Multiple Myeloma, or Head and Neck] • Patient must have an available therapeutic trial, identified through pre-screening/medical record review • Resident of Maryland • Patient, if applicable based on their scores for the Control Preferences Scale, can identify a decision partner. • Must have completed Control Preferences Scale • Able to read, write, and understand in English	• Must be 18 years or older • Able to read and write in English • Identified by the patient

CHAPTER I: Introduction and Background References

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CHAPTER II: Dissertation Methodology References

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Wenzel, J. A., Mbah, O., Xu, J., Moscou-Jackson, G., Saleem, H., Sakyi, K., & Ford, J. G. (2015). A model of cancer clinical trial decision-making informed by African American cancer patients. *Journal of Racial and Ethnic Health Disparities*, *2*(2), 192-199.

CURRICULUM VITAE

PERSONAL DATA

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EDUCATION AND TRAINING

Dates Attended	Degree, Academic Major (Concentrations), School, City, State, Country Year Degree Awarded
2015-Present	**Doctor of Philosophy (PhD) Candidate**, Nursing (Concentrations: Cancer Research, Decision Sciences, Bioethics) Johns Hopkins University School of Nursing Baltimore, Maryland, United States Expected: 2018
2011-2012	**Masters of Science in Nursing (MSN)** (Concentrations: Clinical Leadership, Education) University of North Carolina at Chapel Hill School of Nursing Chapel Hill, North Carolina, United States, Awarded: December 2012
2005-2009	**Bachelor of Science in Nursing (BSN)** University of North Carolina at Chapel Hill School of Nursing Chapel Hill, North Carolina, United States Awarded: May 2009
2006	**Southeast Asian Studies (UNC-Chapel Hill Study Abroad Immersion Program)** National University of Singapore, Singapore, Singapore Completed: August 2006

LICENSURES AND CERTIFICATIONS

2015-Present Maryland RN Licensure Compact from NC, Exp: 9/30/2018

2012-Present Oncology Nursing Certification Corporation, Blood and Marrow Transplant Certified Nurse, Exp: 09/30/2018

2012-Present American Nurses Credentialing Center, Certified Clinical Nurse Leader, #11140002, Exp: 12/31/2018

2011-Present Association of Pediatric Hematology/Oncology Nurses, Certified Chemotherapy and Biotherapy Provider, Exp: 12/31/2019

2009-Present North Carolina RN License #232629, Exp: 9/30/2018

2009-Present American Heart Association BLS for Healthcare Providers, Exp: 03/31/2019

SELECTED PROFESSIONAL EXPERIENCE:

Position, Duties, Accomplishments	Employer	Dates
Johns Hopkins University, Schools of Medicine, Public Health, and Nursing Johns Hopkins Discovery Research Team: United in Faith, Health, and Strength: Pioneering Faith-Centered, Community-Based Advance Care Planning Within African American Churches *-Doctoral Research Assistant; 10 hours/week* Contribute to the science of community-based health equity research in palliative care and end-of- life decision-making. Duties include qualitative coding; data processing; developing cross-cultural surveys; implementing various research methodologies including survey administration, in-depth interviews, and focus groups; creating graphic data summaries, analysis and report writing; conducting systematic literature reviews; co-authoring relevant manuscripts; conducting community-based participatory research using a multi-disciplinary approach; managing timelines.	Principal Investigator: Rebecca Aslakson, MD, PhD, FAAHPM Associate Professor Johns Hopkins University Schools of Medicine and Public Health	2016-Present
Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, School of Medicine, School of Nursing	Site Principal Investigator:	2015-Present

Enhancing Minority Participation in Clinical Trials-EMPaCT: Phase II Study (NIH/NIMHD 7U24MD006970-04); Decision Navigation for Advanced Prostate Cancer Treatment Options using mHealth Research Study-CHAMPION (NIH/NINR 1R01NR016483-01A1) *-Doctoral Research Assistant; 10-20 hours/week* Primary research assistant for the research studies, assisting with various components including prescreening of medical records for eligible research participants, meeting biweekly with the principal investigator and study team to discuss research assignments, gathering and analyzing data, conducting qualitative interviews and administering surveys, collaborating with the biostatistician, editing and serving as a co-author of manuscripts for journal submissions, preparing literature reviews and IRB submissions, managing project timelines, and mentoring pre-licensure and junior doctoral students.	Jennifer Wenzel, PhD, CCM, RN, FAAN Associate Professor Johns Hopkins University School of Nursing, Johns Hopkins Hospital Cancer Prevention and Control Program

OTHER PROFESSIONAL EXPERIENCE:

Position, Duties, Accomplishments	Employer	Dates
Johns Hopkins University, School of Nursing Department of Community-Public Health *-Doctoral Research Assistant; 3-5 hours/week* Collaborate with faculty to engage in research, quality analysis, and publication of scholarship on leadership strategies to promote health work force effectiveness; leadership within cultural context, and leadership development.	Faculty Supervisor: Victoria Hughes, DNS, CNS Assistant Professor Johns Hopkins University School of Nursing	2017-Present

University of North Carolina at Chapel Hill, **School of Nursing** Division of Adult and Geriatric Health -*Adjunct Faculty Member; 2-5 hours/week* Collaborate with UNC faculty to engage in cross- disciplinary research projects. Lecture in nursing courses, provide mentorship and support to graduate and undergraduate honors students, and co-author relevant manuscripts and scholarly presentations in oncology, diversity/inclusion, nursing education, and leadership.	Primary Faculty Liaison: Ashley Leak Bryant, PhD, RN Assistant Professor University of North Carolina at Chapel Hill, School of Nursing	2017-Present
Johns Hopkins University, School of Nursing Doctoral Interest Group -*Graduate Student Coordinator; 5 hours / week* Developed informational workshops for Masters students related to doctoral education options in Nursing, with specific focus on the PhD. Workshops designed to increase exposure to and interest in research and assist students with strategies for preparing competitive applications to doctoral programs. Provided peer mentorship, assisted in interpreting the professional graduate education culture, and served as an ambassador to the Doctoral Program Student Office and Office of Admissions at JHU School of Nursing in recruiting prospective doctoral students.	Program Director: Sarah Szanton, PhD, ANP, FAAN Professor and PhD Program Director Johns Hopkins University School of Nursing	2016

Johns Hopkins University, School of Nursing Parent and Family Responses to a Child Undergoing Bone Marrow Transplantation During Transitions in Care (NIH/NINR, F31 NR014751-01A1). *-Doctoral Research Assistant; 2 hours/week* Assisted the principal investigator and co-investigator in identifying and corresponding with research study participants for qualitative interviews in at the Johns Hopkins Children's Hospital to obtain data for an NIH-supported research study; obtaining written consent forms.	Co-Principal Investigator: Katherine Heinze, PhD, RN Hecht-Levi Postdoctoral Fellow Johns Hopkins University Berman Institute for Bioethics	2016
UNC Chapel Hill, School of Nursing Division of Family Health; Division of Adult and Geriatric Health *-Clinical Faculty (Instructor), Course Coordinator; 40 hours/week (full-time)* Taught in class, clinical, and laboratory settings specializing in pediatric, adult, family, acute care, and oncology populations. Managed Health Assessment Course and supervised 8 Clinical Lab Instructors. Accomplishments: appointed as Faculty Liaison to the UNC Health Care Professional Development Committee; Elected Clinical Faculty Representative to the Structure, Governance, and Strategic Planning Committee; recipient of 2015 UNC Health Care Nurse Faculty of the Year Award.	Former/Hiring Dean: Kristen Swanson Dean and Professor Seattle University College of Nursing	2013-2015
Duke University Medical Center Pediatric Blood and Marrow Transplant Unit *-Nurse Clinician III; 40 hours/week* Registered Nurse managing ongoing care of patients (newborns to young adults) undergoing inpatient transplantation and acute hematology-oncology care. Duties include comprehensive health assessments; implementation of medical and nursing orders; administration and management of intensive medication therapies including clinical trial study	Division Chief: Paul Martin, MD, PhD Division Chief Pediatric Blood and Marrow Transplant Unit 5200 Duke University Medical Center Nurse Manager: Kristin Ammon, MSN, RN Duke University Medical Center	2009-2015

	protocols; management of transplant side effects, immunosuppression, and electrolyte abnormalities, development of nursing care plans; provided ongoing education for patients, families, and caregivers; preceptor to new nurses; charge nurse. Accomplishments include: Co-Chair of the HUGS Palliative Care Committee; Co-Chair of the Patient and Family Education Committee; Nursing Representative to the Patient and Family Centered Care Committee at Duke Children's Hospital.	2301 Erwin Road Pediatric Blood and Marrow Transplant Unit 5200

SPONSORED PROJECTS - GRANTS AWARDED

2018	Role of Decision Partners in Cancer Clinical Trial Participation, PI: Tamryn Gray, National Cancer Institute Center to Reduce Cancer Health Disparities, Geographic Management of Cancer Health Disparities Program Region 1 North Research Project Support Program, Role: Principal Investigator, Cost: $10,000.
2017-2019	Clinical Trial Participation among Adults with Cancer and Decision Partners, PI: Tamryn Gray, American Cancer Society - Doctoral Degree Grant in Cancer Nursing, #130861-DSCN-17-074-01-SCN, Role: Principle Investigator, Cost: $30,000.
2017-2019	Decision Partner Involvement in Cancer Patient Decisions about Clinical Trial Participation, PI: Tamryn Gray, Oncology Nursing Society Foundation Endowment Dissertation Research Grant, Role: Principal Investigator, Cost: $5,000.
2013-2015	Careers Beyond the Bedside (CaBB), PI: Pamela Rowsey, Effort: 15%, Health Resources and Services Administration Grant# D19HP2498. Role: Co-Investigator. Cost: $640,000

OTHER PROJECTS

Under Review	EMBRACE: Center of Excellence for Valuing Effects of Illness on Caregivers and Family Members. PI: Eve Wittenberg, Center for Health Decision Sciences, Harvard T.H. Chan School of Public Health, PhRMA Foundation, Role: Center Advisory Board Member.
2016-Present	Decision Navigation for Advanced Prostate Cancer Treatment Options using mHealth (CHAMPION), National Institutes of Health / National Institute for

	Nursing Research, 1R01NR016483-01A1, PI: Randy Jones, University of Virginia; Site PI: Jennifer Wenzel, Johns Hopkins University, Role: Doctoral Research Assistant. Cost: $2,187,000
2016-Present	Individual Characteristics and Research Decisions in Cancer Care at Johns Hopkins, PI: Dina Lansey, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. Role: Research Assistant.
2012	Masters Thesis Study: Teaching in the Fast Lane: Preparing Nursing Faculty to Teach Accelerated Baccalaureate Nursing Students. Advisor: Meg Zomorodi, Role: Principal Investigator.

ACADEMIC AWARDS, HONORS, AND FELLOWHIPS

National / International – Academic/Research

2018-2019	Training Awardee, MGH Workshop on Research Methods in Supportive Oncology, Massachusetts General Hospital (MGH) / Harvard Medical School, Boston, MA. One-year mentored research development program funded by the National Cancer Institute (NCI R25) (Nationally Competitive Application Process)
2017-2018	Isabel Hampton Robb Memorial Scholar, Nurses Educational Funds, Inc. (NEF) awarded to the NEF scholarship applicant with the highest evaluation score for academic excellence and potential to contribute to the nursing profession ($10,000)
2017-2018	Bioethics Boot Camp Fellowship, University of Pennsylvania Department of Medical Ethics & Health Policy, one of seven competitively selected scholars in law, humanities, and social sciences for yearlong program to cultivate future scholarship and leadership in bioethics research and practice, funded by The Greenwall Foundation ($4,000)
2017-2019	American Cancer Society Pre-Doctoral Research Fellowship ($30,000)
2016-2018	Johnson & Johnson Campaign for the Future of Nursing /American Association of Colleges of Nursing Minority Nurse Faculty Scholar ($36,000)
2016-2018	Jonas Nurse Leader Scholar, Jonas Center for Nursing and Veterans Healthcare ($20,000)
2015-2018	Robert Wood Johnson Foundation - Future of Nursing Scholar ($125,000)

National / International - Other

2017	Inaugural Compassion in Action Healthcare Conference Scholarship Recipient, The Schwartz Center for Compassionate Healthcare, Boston, MA
2016	Invited Doctoral Scholar, 23rd Institute on Teaching and Mentoring, The Compact for Faculty Diversity
2016	Emerging Leader, American Association of Colleges of Nursing - Graduate Nursing Student Academy
2015-2016	Awardee, National League for Nursing 2015 LEAD Leadership Institute, Leadership Development Program for Emerging Nurse Leaders (National Competitively Selected Participant)
2013-2015	Invited, Inaugural Oncology Nursing Certification Corporation (ONCC) Test Development Committee Member**,** Blood and Marrow Transplantation Certified Nurse Exam

Regional

Dec 2017	Mentor of the Month, University of Maryland, Baltimore, CURE Scholars Program: An initiative to increase diversity in the biomedical research and health workforce as upstream pathway to address cancer workforce diversity and cancer health disparities. Program participants are promising inner-city Baltimore middle school students receiving STEM enrichment, professional development, and mentorship. Funded by the NCI Center to Reduce Cancer Health Disparities
July 2017	NCI GMaP Travel Scholarship, National Cancer Institute - Geographic Management of Cancer Health Disparities Program (GMaP) - Region 1 North to attend the National Cancer Institute Center to Reduce Cancer Health Disparities (NCI CRCHD) Career Development and Scientific Workshop – Grant writing (Regional Scholarship, $1,000)
March 2017	NCI GMaP Travel Scholarship, National Cancer Institute - Geographic Management of Cancer Health Disparities Program (GMaP) - Region 1 North to present at the 2017 American Association for Cancer Research Annual Meeting (Regional Scholarship, $1,000)
2016-2018	Scholar, Southern Regional Education Board (SREB) Doctoral Scholars Program (Nominated by Dean & Executive Vice Dean, Johns Hopkins School of Nursing)
2015	UNC Health Care Nurse Faculty of the Year Award for excellence in teaching and promoting education for nursing staff and students across the health system

2011-2012 Nurse Educators of Tomorrow Scholar, College Foundation of North Carolina (State-wide, full-tuition scholarship to earn Masters of Science in Nursing)

Johns Hopkins University

2018 Innovators Award, Leadership Team – Black Student Nurses Association, Johns Hopkins University School of Nursing

2017 Visiting Pre-Doctoral Scholar, Centre for Improving Palliative, Aged, and Chronic Care through Clinical Research and Translation – IMPACCT, University of Technology Sydney, NSW, Australia, January 13th – 24th, 2017. One individual selected annually by JHUSON Dean from among School research faculty and students.

2015 Inductee, Sigma Theta Tau International Honor Society for Nursing- Nu Beta Chapter

Duke University Medical Center

2010 Nursing Staff Leadership Luncheon Awardee, Duke University Hospital

University of North Carolina at Chapel Hill

2015 Carrington Professional Development Faculty Travel Award, UNC-Chapel Hill School of Nursing

2013 Inductee, Sigma Theta Tau International Honor Society for Nursing- Alpha Chapter, Membership #1095355

2012 Brummett-Kemble Scholarship, UNC-Chapel Hill School of Nursing

2012 Annie Lathan Odom-Hayes Travel Scholarship, UNC-Chapel Hill School of Nursing

2011-2012 Alison F. Yeargan Master of Science in Nursing Scholarship, UNC-Chapel Hill School of Nursing

2009 Chancellor's George Livas Award for Most Outstanding Student, UNC School of Nursing

2009 Invited Keynote Speaker, Closing the Academic Achievement Gap Awards Ceremony (selected by Superintendent of Alamance-Burlington School System)

2007	Invited Keynote Speaker, UNC FedEx Global Education Building Grand Opening (selected by former UNC-Chapel Hill Chancellor James Moeser)
2006	Southeast Asia Summer Immersion Program Scholar, National University of Singapore, Singapore
2005-2009	James M. Johnston Scholarship, University of North Carolina at Chapel Hill (Full-tuition Merit Based Scholarship)

SHORT TERM RESEARCH AND PROFESSIONAL DEVELOPMENT ACTIVITIES

February 2017	Psychosocial Oncology Institute, 1-Day Training American Psychosocial Oncology Society, Orlando, FL Training Leaders: Paul Jacobsen, PhD; Lori Wiener, PhD, DCSW, LCSW-C; Joseph Greer, PhD
August 2016	Roter Interaction Analysis System (RIAS) for Oncology Consultation, 2-Day Training Johns Hopkins Bloomberg School of Public Health, Baltimore, MD Training Leaders: Debra Roter, DrPH
June 2016	Family Research – Conceptual and Methodological Issues, 5-Day Training University of North Carolina at Chapel Hill, Chapel Hill, NC Training Leaders: Kathleen Knafl, PhD; Janet Deatrick, PhD, RN
June 2016	Mixed Methods for Research in Public Health, 4-Day Training Johns Hopkins Bloomberg School of Public Health, Baltimore, MD Training Leaders: Joseph Gallo, MD, MPH; Britt Dahlberg, PhD

PROFESSIONAL SOCIETY MEMBERSHIPS AND COMMITTEE MEMBERSHIPS

2017-Present	American Society of Clinical Oncology, *Member*
2017-Present	American Academy of Hospice and Palliative Medicine, *Member*
2017-Present	Hospice and Palliative Nurses Association, *Member*
2017-Present	Cancer Outcomes and Health Services Outcomes Research Interest Group, Johns Hopkins University, *Member*
2017-Present	American Psychosocial Oncology Society (APOS), *Member, Conference Volunteer (2017, 2018), Research Committee Member (2017-Present); Program Committee (2017-Present)*

2016-Present	American Association for Cancer Research (AACR), *Associate Member*
2016-Present	American Society for Bioethics and Humanities (ASBH), *Member*
2016-Present	International Council on Women's Health Issues (ICOWHI), *Member*
2016-Present	Society for Judgment and Decision-Making (SJDM), *Member*
2016-Present	Cancer Epidemiology, Prevention, and Control Research Interest Group, Johns Hopkins Bloomberg School of Public Health, *Member*
2016-Present	International Family Nursing Association (IFNA), *Member*
2016-Present	Children's Oncology Group (COG), *Member*
2015-Present	Sigma Theta Tau Nursing Society – Nu Beta Chapter, *Member*, *Executive Board Member (2016-2017)*
2013-2018	Sigma Theta Tau Nursing Society – Alpha Alpha Chapter, *Governance Committee Member*
2010-Present	Oncology Nursing Society (ONS), *Member*
2010-Present	Association of Pediatric Hematology and Oncology Nurses (APHON), *Member*

LEADERSHIP AND SERVICE ACTIVITIES

Academic and Professional Service

2017-Present	Mentor-Coach and Leadership Council Advisor, University of Maryland, Baltimore, CURE Scholars Program: An initiative to increase diversity in the biomedical research and health workforce as upstream pathway to address cancer workforce diversity and cancer health disparities. Program participants are promising inner-city Baltimore middle school students receiving STEM enrichment, professional development, and mentorship. Funded by the NCI Center to Reduce Cancer Health Disparities.
2017	Invited Panelist, Alumni Board, Johns Hopkins University School of Nursing

2016	Invited Panelist, National Advisory Board, Johns Hopkins University School of Nursing
2016	Conference Planning Committee, Partnering with Patients in Decision Making Inaugural Conference
2016-Present	Advisory Committee Member, Maryland Higher Education Commission, Nurse Faculty for the Future Grant Program, Johns Hopkins University School of Nursing.
2016-Present	School of Nursing Representative, Johns Hopkins University Student Services Excellence Initiative Advisory Committee (Appointed by the Johns Hopkins Board of Trustees), Term ends: 2018.
2016-Present	Independent Peer Abstract Reviewer, American Association for Cancer Education - International Cancer Education Conference, Cancer Patient Education Network
2016-Present	Liaison, American Association of Colleges of Nursing (AACN) - Graduate Nursing Student Academy (GNSA) - national organization promoting career planning, professional/leadership development, and health policy engagement among graduate students in nursing, Term ends: 2018.
2016-Present	Executive Board Member / Public Relations Chair, Biomedical Scholars Association, Johns Hopkins University, (interdisciplinary health and biomedical research student society)
2015-Present	Executive Board Member, Black Student Nurses Association, Johns Hopkins University School of Nursing
2014-2015	Diversity Faculty Committee, University of North Carolina at Chapel Hill
2014-2015	Elected Clinical Faculty Representative to Structure, Governance, and Strategic Planning Committee, UNC School of Nursing
2013-2015	Faculty Liaison, UNC Healthcare Nursing Professional Development Committee
2013-2015	Test Development Committee Member, Oncology Nursing Certification Corporation for the new Blood and Marrow Transplantation Certified Nurse Exam
20014-2015	Nursing Representative, Duke Hospital Patient- and Family-Centered Care Committee (Hospital-wide)
2009-2015	Member, Co-Chair (2012-2015), HUGS Palliative Care Committee, Duke Pediatric BMT Unit

2010-2015	Member, Co-Chair (2013-2015), Patient Education Committee, Duke Pediatric BMT Unit
2012-2015	Item Writer, Oncology Nursing Certification Corporation for the new Blood and Marrow Transplantation Certified Nurse Exam
2009-Present	Board Member, UNC School of Nursing Alumni Association, Board of Directors (Graduate Student Representative, 2011-2012)
2009-Present	Panelist, Annual Alumni Panel, UNC School of Nursing Undergraduate Academic Program
2010-2015	Medical Team Member, World Overcomers Christian Church
2008-2009	Community Outreach Chair, Association of Nursing Students, University of North Carolina at Chapel Hill

EDITORIAL ACTIVITIES

2017-Present	Reviewer for *Psycho-Oncology* journal
2016-Present	Reviewer for *Ethnicity and Health* journal

SCIENTIFIC PRESENTATIONS

Podium Presentations - Conference Proceedings

Gray, T.F., Clayman, M. (October 2017). *Engaging Decision Partners in Cancer Patient Decisions about Clinical Trial Participation.* Podium Presentation. International Conference on Communication in Healthcare (ICCH) & Health Literacy Annual Research Conference (HARC), 2017. Baltimore, MD.

Gray, T.F. (July 2017). *Patient Preferences and Decision Partner Involvement in Cancer Clinical Trial Participation.* Podium Presentation. Robert Wood Johnson Foundation (RWJF) Future of Nursing Scholars Program Summer Institute. Washington, DC.

Podium Presentation - Invited

Gray, T.F. (September 2017). *Patient Preferences for Decision Partner Involvement in Decisions about Clinical Trial Participation.* Invited Podium Presentation. Emory University Winship Comprehensive Cancer Center. Atlanta, GA.

Gray, T.F. (June 2017). *Deciding Under Uncertainty. Fighting for Two: Shared Decision-Making in Future Fertility Choices in Women with Cancer.* Invited Podium Presentation. University of Pennsylvania Department of Medical Ethics and Health Policy. Philadelphia, PA.

Gray, T.F. (January 2017). *Decision Partner Involvement in Cancer Clinical Trial Participation*. Invited Podium Presentation. Research Summer School. Centre for Cardiovascular and Chronic Care, University of Technology Sydney. Sydney, New South Wales, Australia.

Gray, T.F., Hodges, E. (September 2014). *Stand Up and Lead for a Healthier Tomorrow: Nursing in the 21st Century.* Invited Podium Presentation. University of North Carolina at Chapel Hill School of Nursing. Chapel Hill, NC.

Fowler, T. (October 2012). *What About Nursing? A Career of Endless Opportunities.* Invited Podium Presentation. Presented at the University of North Carolina at Chapel Hill. Chapel Hill, NC.

Poster Presentations – Conference Proceedings

Bryant, A., Gosselin, T., Coffman, E., Phillips, B., **Gray, T.F.,** Knafl, G. (May 2018). *Symptoms, Functional Status, and Quality of Life of Adults with Acute Leukemia During Induction Treatment: A Longitudinal Examination.* Conference Presentation. Oncology Nursing Society 43rd Annual Congress. Washington, DC.

Sloan, D.H., **Gray, T.F.,** Harris, D. (October 2017). *Attitudes, Beliefs, and Barriers to Advanced Care Planning: A Preliminary Look at the Views of African-American Parishioners.* Accepted for poster presentation. International Conference on Communication in Healthcare (ICCH) & Health Literacy Annual Research Conference (HARC). Baltimore, MD.

Gray, T.F., Cudjoe, J., Han, H.R., Wenzel, J., Thorpe, R.J., Murphy, J. (April 2017). *Have You Checked? Disparities in Cancer Screening Practices among Minority Populations.* Poster Presentation. American Association for Cancer Research, AACR, Annual Meeting 2017. Washington, DC.

Gray T.F. (November 2016). *The Role of Shared Decision-Making in Future Fertility Choices among Women with Cancer.* Poster Presentation. International Council on Women's Health Issues Conference, ICOWHI, 2016. Baltimore, MD.

Gray, T.F., Hodges, E. A, Rowsey, P.J., Kneipp, S., Woods-Giscombe, C., Foster, B., Alexander, R., & Kowlowitz, V. (November 2016). *Bridging the Gender Divide: Facilitating the Educational Path for Men in Nursing.* Poster Presentation. American Association of Colleges of Nursing, AACN, Baccalaureate Education Conference. Anaheim, CA.

Gray, T.F., Alderman, J. (September 2016). *Beyond the Expected: Nursing's Endless Possibilities.* Poster Presentation. National League for Nursing, NLN, Summit 2016. Conference Theme: Beyond Boundaries: Programming that meets the needs of nurse educators in many different stages of their careers and with different levels of expertise in the topics that are most critical to nursing education. Orlando, FL.

Gray, T.F. (November 2014). C*areers Beyond the Bedside (CaBB): An Intervention to Increase Diversity at All Levels in Nursing*. Poster Presentation. American Association of Colleges of Nursing, AACN, Baccalaureate Education Conference. Baltimore, MD.

RESEARCH INTERESTS

Keywords: cancer prevention and control, health disparities, cancer treatment decision-making clinical trial participation; patient-family centered care, palliative care, bioethics, patient reported outcomes, financial toxicity, end-of-life, blood and marrow transplantation, oncofertility, health services research, implementation science, health policy; health professions education

BIBLIOGRAPHY

Invited Book Chapters

Gray, T.F., Chapter 51: Pediatric Oncology (Submitted 2017). In Nettina, S. (Ed.) Lippincott Manual of Nursing Practice. Lippincott, Williams & Wilkins, Ambler: Pennsylvania.

Publications in Peer-Reviewed Journals

Storey, S., **Gray, T.F.,** Bryant, A.L. (2017). Comorbidity, physical function, and quality of life in older adults with acute myeloid leukemia. *Current Geriatrics Reports.* Doi: 10.1007/s13670-017-0227-8.

Gray, T.F., Cudjoe, J., Murphy, J., Thorpe, R.J., Wenzel, J., Han, H.R. (2017). Cancer screening practices among minority and underrepresented populations. *Seminars in Oncology Nursing: Special Issue on Cancer Screening and Early Detection, 33(2):184-198.* Doi: 10.1016/j.soncn.2017.02.008.

Gray, T.F. (2017). Clinical moment: How can I change my patient's treatment decisions by becoming a nurse scientist? *Clinical Journal of Oncology Nursing, 21(2), 263.* Doi: 10.1188/17.CJON.263.

Hodges, E.A., Rowsey, P.J., **Gray, T.F.,** Kneipp, S., Woods-Giscombe, C., Foster, B., Alexander, R., Kowlowitz V. (2017). Bridging the gender divide: Facilitating the educational path for men in nursing. *Journal of Nursing Education, 56(5)*, 295-299. Doi: 10.3928/01484834-20170421-08.

Woods-Giscombe C. L., Rowsey, P. J., Kneipp, S. M., Owens, C., Sheffield, K., Galbraith, K., Hammad, S., **Fowler, T.,** Hodges, E., Kowlowitz, V., & Alexander, G. R. (2015). Underrepresented students' perspectives on institutional climate during application and admission to nursing school: Implications for enhancing diversity and inclusion. *Journal of Nursing Education, 54*(5), 261-269. Doi: 10.3928/01484834-20150417-03.

Kneipp, S.M., Rowsey, P.J., Giscombe, C.L., Hodges, E.A., **Fowler, T.,** Alexander, R. (2014). Countering the influence of cultural hegemony on choosing a nursing career: a group-mentoring approach for student recruitment. *Journal of Nursing Education, 53*(5), 296-9. Doi: 10.3928/01484834-20140408-02.

Publications in Peer-Reviewed Journals (In Press)

Kowlowitz, V., Johnson Rowsey, P., Byrns, P., Woods-Giscombe, C., Kneipp, S.M., Page, J., **Gray, T.F.** (In Press). Careers beyond the bedside: an effective program to increase diversity in nursing. *Journal of Cultural Diversity*.

Bryant, A.L., Gosselin, T., Coffman, E., Phillips, B., Hines, K., **Gray, T.F.**, Klepin, H., Wood, W., Muss, H., Reeve, B.B. (In Press). Longitudinal Weekly Assessment of Symptoms, Mobility and Function, and Quality of Life in Adults with Acute Leukemia during their Initial Hospitalization of Approximately 30 Days. *Oncology Nursing Forum.*

Publications in Peer Reviewed Journals (Presentation Abstracts)

Gray, T.F., Cudjoe, J., Han, H.R., Wenzel, J., Thorpe, R.J., Murphy, J. (2017) Have you checked? Disparities in cancer screening practices among minority populations. *Cancer Research, 77(13)*, 5293-5293. DOI:10.1158/1538-7445.AM2017-5293.

TEACHING ACTIVITIES

Johns Hopkins University

Spring 2018	NR 110.591 Death and Dying: Personal and Professional Perspectives, *Guest Lecturer*, Graduate Level, 2 credits, Course Coordinator: Jennifer Wenzel, PhD, RN, CCM, FAAN
Summer 2017	NR 110.591 Death and Dying: Personal and Professional Perspectives, *Guest Lecturer*, Graduate Level, 2 credits, 6 students, Course Coordinator: Jennifer Wenzel, PhD, RN, CCM, FAAN
Spring 2017	NR 110.591 Death and Dying: Personal and Professional Perspectives, *Guest Lecturer and Simulation Co-Designer*, Graduate Level, 2 credits, 18

	students, Course Coordinators: Valerie Cotter, DrNP, AGPCNP-BC, FAANP and Jennifer Wenzel, PhD, RN, CCM, FAAN.
Spring 2016	NR110.491/NR 110.591 Death and Dying: Personal and Professional Perspectives, *Course Co-Developer and Teaching Assistant*, Undergraduate / Graduate Level, 1 credit, 20 students, Course Coordinators: Dean Patricia Davidson, PhD, MEd, RN, FAAN and Executive Vice Dean Marie Nolan, PhD, MPH, RN, FAAN, Rating: 4.65/5.00.

University of North Carolina at Chapel Hill

Spring 2016	"Leading Change," N588 Leadership in Health Care Organizations, *Guest Lecturer,* Senior Undergraduate Level, 4 credits, 120 students, Course Coordinator: Jennifer Alderman, MSN, RN.
Spring 2016	"Non-traditional Roles in Nursing," N588 Senior Nursing Leadership Course. *Guest Lecturer*. Senior Undergraduate Level, 4 credits, 120 students, Course Coordinator: Jennifer Alderman, MSN, RN.
Summer 2015	"Nursing Management of Cancer," N364 Nursing Care of Adults with Major Health Problems, I. *Guest Lecturer*. Undergraduate Level, 6 credits, 80 students, Course Coordinator: Christina Leonard, MSN, RN.
Summer 2015	N366.001 Health Assessment, *Course Coordinator,* Undergraduate Level, 3 credits, 142 students, supervised 8 faculty, Rating: 4.51/5.00.
Summer 2015	N366.507 Health Assessment Lab, *Instructor,* Undergraduate Level, 3 credits, 10 students, Rating: 4.76/5.00.
Summer 2015	N366.510 Health Assessment Lab, *Instructor,* Undergraduate Level, 3 credits, 8 students, Rating: 4.81/5.00.
Spring 2015	"Leading Change," N588 Leadership in Health Care Organizations. *Guest Lecturer*. Undergraduate Level, 4 credits, 130 students, Course Coordinator: Jennifer Alderman, MSN, RN.
Spring 2015	N366.507 Health Assessment Lab, *Instructor,* Undergraduate Level, 3 credits, 8 students, Rating: 4.88/5.00. Joan Williams, MSN, RN.
Spring 2015	N366.503 Health Assessment Lab, *Instructor,* Undergraduate Level, 3 credits, 10 students, Rating: 4.89/5.00. Course Coordinator: Joan Williams, MSN, RN.
Fall 2014	"Nursing Management of Cancer," N364 Nursing Care of Adults with Major Health Problems, I. *Guest Lecturer*. Undergraduate Level, 6 credits, 83 students. Course Coordinator: Christina Leonard, MSN, RN.

Fall 2014	N472.604 Nursing Care of Infants, Children, and Their Families, *Clinical Instructor*, Undergraduate Level, 5 credits, 9 students, Rating: 4.20/5.00. Course Coordinator: Lisa Woodley, MSN, RN
Fall 2014	N472.702 Nursing Care of Infants, Children, and Their Families, *Clinical Instructor*, Undergraduate Level, 5 credits, 8 students, Rating: 4.20/5.00. Course Coordinator: Lisa Woodley, MSN, RN
Spring 2014	N366.503 Health Assessment Lab, *Instructor,* Undergraduate Level, 3 credits, 9 students, Rating: 4.57/5.00.
Summer 2014	"Nursing Management of Cancer," N364 Nursing Care of Adults with Major Health Problems, I. *Guest Lecturer*. Undergraduate Level, 6 credits, 81 students, Course Coordinator: Christina Leonard, MSN, RN.
Summer 2014	N364.603 Nursing Care of Adults with Major Health Problems I, *Clinical Instructor*, Undergraduate Level, 6 credits, 5 students, Rating: 4.71/5.00. Course Coordinator: Christina Leonard, MSN, RN.
Spring 2014	"Nursing Care and Management for Hematologic/Oncology Patients," N591 Nursing Care of Adults with Major Health Problems, II. *Guest Lecturer.* Senior Undergraduate Level, 6 credits, 40 students, Course Coordinator: Meg Zomorodi, PhD, RN.
Spring 2014	N472.801 Nursing Care of Infants, Children, and Their Families, *Clinical Instructor*, Undergraduate Level, 5 credits, 7 students, Rating: 4.80/5.00. Course Coordinator: Lisa Woodley, MSN, RN
Fall 2013	"Cancer Chemotherapy," N362 Pharmacology across the Lifespan, *Guest Lecturer,* Undergraduate Level, 3 credits, 80 students, Course Coordinator: Nancy Crowell, MSN, AGPCNP-BC.
Fall 2013	N472.701 Nursing Care of Infants, Children, and Their Families, *Clinical Instructor*, Undergraduate Level, 5 credits, 9 students, Rating: 4.39/5.00. Course Coordinator: Lisa Woodley, MSN, RN
Fall 2013	N472.802 Nursing Care of Infants, Children, and Their Families, *Clinical Instructor*, Undergraduate Level, 5 credits, 8 students, Rating: 4.04/5.00. Course Coordinator: Lisa Woodley, MSN, RN
Summer 2013	"Nursing Management of Cancer," N364 Nursing Care of Adults with Major Health Problems I, *Guest Lecturer*, Undergraduate Level, 6 credits, 81 students, Course Coordinator: Christina Leonard, MSN, RN.
Summer 2013	N364 Nursing Care of Adults with Major Health Problems I, *Clinical Instructor*, Undergraduate Level, 6 credits, 7 students, Rating: 4.75/5.00. Course Coordinator: Christina Leonard, MSN, RN